The Thesis Committee for Shawn James Scott
Certifies that this is the approved version of the following thesis:

The Effects of Walking Speed and an Uneven Surface on Dynamic Stability Margins in Young Adult Subjects with and without Traumatic Unilateral Trans-Tibial Amputations

APPROVED BY
SUPERVISING COMMITTEE:

Supervisor: ____________________________
Jonathan B. Dingwell

____
Larry Abraham

The Effects of Walking Speed and an Uneven Surface on Dynamic Stability Margins in Young Adult Subjects with and without Traumatic Unilateral Trans-Tibial Amputations

by

Shawn James Scott BA, MPT

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Dedication

I would like to take this opportunity to dedicate this work to the Service members of the United States who will always fight to defend our freedom and way of life. It is my ongoing devotion to them that compelled me to push on through personal challenges. The affection of my wife, Laura, and my four sons often buoyed my spirits throughout this time. As I worked to complete this document, they provided infinite reminders of what is truly important in life.

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Abstract

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Shawn James Scott, M.A.
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Supervisor: Jonathan B. Dingwell

Abstract: Dynamic stability is commonly defined as the ability to maintain balance through center of mass control during locomotion. Patients with locomotor impairments are especially challenged when walking over uneven surfaces (Richardson 2004). We studied dynamic stability margins in young healthy adults and in adults with unilateral traumatic trans-tibial amputations (TTA). To date, studies have not controlled for walking speed over an uneven surface in a patient population. We hypothesized that: 1) DSMs would increase over the uneven rocky surface (URS) for both groups, 2) DSMs would be greater on the involved side at faster walking speeds for subjects with TTA and, 3) DSMs would increase more for the involved limb when on the URS. 17 (4 females, 13 males) young healthy military service members (22.8 ± 6.4 years) and 12 (1 female, 11 males) service members (27.2 ± 4.7 years) with traumatic unilateral trans-tibial amputations participated in two study designs. A 15-segment model was used to estimate whole body COM motions. All subjects walked at 5 dimensionless speeds over a flat level surface (FLS) and an URS. Subjects completed 6-10 trials over each surface at each speed. Minimum frontal plane DSM values were extracted for each stride for statistical analyses. For young healthy subjects a two factor (speed x surface) ANOVA was used to test significance ($p<.05$). The DSMs were not greater over the URS ($p=.307$), but a main effect due to speed was found ($p<.001$) for young healthy subjects. In contrast, DSMs were significantly larger when subjects with TTA walked on the URS compared to the FLS ($p = 0.011$). For subjects with unilateral TTA, a three-factor ANCOVA ((amputation) side x speed x surface) with residual limb length ($p=.029$) and time in prosthesis ($p=.741$) as covariates was used for hypothesis testing. When limb length and time in prosthesis were accounted for there was no significant within subjects effect due to speed ($p=.656$). There were no significant differences between involved and uninvolved limbs ($p = 0.211$). There were no significant interaction effects. In conclusion, there was a difference in DSMs due to speed in unimpaired subjects and due to surface and residual limb length in subjects with unilateral TTAs. In subjects with unilateral TTA side-to-side symmetry was found for DSM measures, which was in contrast to an earlier study of subjects with unilateral trans-femoral amputations (Hof 2006). It appears that symmetry and dynamic stability are reasonable expectations for young adults with isolated TTAs.

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I. GENERAL INTRODUCTION

Dynamic stability in walking is defined as the ability to resist a perturbation that can lead to a trip, stumble or fall. The purpose of this research is to examine the effects of multiple walking speeds and two surface conditions on dynamic stability margins (DSMs) in young adults with and without traumatic trans-tibial amputations (TTA).

Lower limb amputations (LLA) are life-altering events that result in a significant loss of sensation, strength, and balance. In elderly patients with advanced vascular disease, and in young adults with traumatic amputations, there is an increased risk of falling associated with the loss of a lower extremity (Miller, Speechley et al. 2001; Hof, van Bockel et al. 2007). Falls are a major cause of injury, hospitalization, and death (Thurman, Stevens et al. 2008). This makes fall risk identification and prevention a top priority for rehabilitation specialists who work with patients who have sustained a LLA. Identification of increased fall risk leads to targeted interventions, such as specific strength training, balance training, assistive device prescription, and home health care for those who need them most (Tinetti, Baker et al. 1993; Moirenfeld, Ayalon et al. 2000). In order to correctly identify those who are at increased fall risk, research must be conducted to test and expand on current theories of dynamic stability.

In the presence of LLA, frontal plane balance is especially compromised due to loss of distal proprioception, ankle motor control, and a small base of support (MacKinnon and Winter 1993). Lateral falls are strongly associated with hip fractures and mortality in elderly adults (Greenspan, Myers et al. 1998). While most falls for patients with LLA occur during dynamic activities, such as walking, current clinical measures of fall risk are based primarily on static measures or functional tests that have been validated in the frail elderly (Boulgarides, McGinty et al. 2003; Niino, Kozakai et al. 2003). Due to a high ceiling effect, these same clinical tests do not adequately predict fall risk in young adults with LLA (Gauthier-Gagnon and Grise 2006).

Improving dynamic stability is directly related to closing the gap in function and safety between a person with a LLA and a healthy person. Several methods have been proposed to quantify dynamic stability and predict fall risk, but there is currently no clear consensus on how to measure dynamic stability in humans (Dingwell and Kang 2007a). Two fundamental independent variables related to the investigation of dynamic stability during walking are: 1) the speed of movement and, 2) surface conditions that must be traversed in order to go from one point to another. Dynamic stability can be quantified mechanically as the horizontal distance between an extrapolated center of mass (XcoM) and the margin of the base of support. Dynamic stability margins (DSMs) have been used to explain frontal plane adaptations through increased step width in patients with trans-femoral amputations (Hof, van Bockel et al. 2007). In our research we expanded on the work of Hof (2007) by using a novel research protocol that controls both speed and surface conditions to clearly capture the relationship between speed, surface, and DSMs. From this foundational research, future research may be conducted to determine if affecting DSMs through specific interventions can lead to improvements in dynamic stability (i.e. decreased fall risk).

WALKING SPEED AND FALL RISK

In human walking studies, speed is most often allowed to vary, dependent on surface, age, or pathology (MacKinnon and Winter 1993; Hausdorff, Rios et al. 2001; Menz, Lord et al. 2003; Owings and Grabiner 2004; Richardson, Thies et al. 2004b; Brach, Berlin et al. 2005; Thies, Richardson et al. 2005a; DeMott, Richardson et al. 2007). It is well established that patient populations walk slower than normal (Podsiadlo and Richardson 1991; Richardson, Thies et al. 2004b; Richardson, Thies et al. 2005). Richardson et al. found that preferred walking speed (PWS), over a level surface, was significantly slower for elderly women with peripheral neuropathy (PN) than in age matched women (Richardson, Thies et al. 2004b). In spite of this, several studies have failed to make a connection between slow PWS and moderate to high fall risk subjects with a history of falling, or who fell after being tested (Nakamura, Meguro et al. 1996; Hausdorff, Edelberg et al. 1997; Maki 1997; Hausdorff, Rios et al. 2001; Richardson, Thies et al. 2005; DeMott, Richardson et al. 2007). In another study conducted by Richardson et al., there was no difference in PWS over a level surface in elderly patients with PN and a history of falling in the previous year and those with PN who did not fall (Richardson, Thies et al. 2005). One possible explanation for this is the theory that slow walking may represent an attempt to improve dynamic stability within individuals who fear falling, have fallen, or may be at increased risk of falling (Courtemanche, Teasdale et al. 1996; Maki 1997). The overall conclusion from these studies is that slow PWS over level surfaces does not appear to predict fall risk in community dwelling elderly or in patients with PN.

WALKING SPEED, IRREGULAR SURFACES, AND FALL RISK

Surface conditions play a major role in the planning of step placement and walking speed (Patla, Prentice et al. 1999; Richardson, Thies et al. 2004b). Thies and Richardson et al. made comparisons between young healthy women and elderly healthy women over level and irregular surface conditions while walking at PWS (Thies, Richardson et al. 2005a). The results indicated that elderly subjects without a history of falling adapted a more conservative gait pattern, especially over the irregular surface, which was slower than younger women (Thies, Richardson et al. 2005a). Menz and Lord et al. conducted a similar study in elderly subjects with diabetic PN over a level and irregular surface. They found that differences in slower PWS and step timing variability were greater over the irregular surface in the patient group than in the age matched control subjects without diabetes (Menz, Lord et al. 2003).

Richardson et al. concluded in a study of elderly females, with and without PN, that a challenging surface is more revealing for identifying persons with gait abnormalities than a level surface (Richardson, Thies et al. 2004b). In this study, Richardson found that the challenging surface condition amplified the differences in PWS and step timing variability between unimpaired and impaired subjects. In a separate study by Richardson et al., walking over an irregular surface revealed significantly slower PWS in subjects with PN and a history of falling ($p=.045$) compared to non-fallers with PN (Richardson, Thies et al. 2005). These same measurements were not significantly different when both groups walked over a level surface.

DeMott and Richardson et al. studied walking over level and irregular surfaces in patients with severe PN and then prospectively tracked falls over the subsequent year (DeMott, Richardson et al. 2007). In this study there was no difference between future fallers and non-fallers in PWS or step time variability over a level surface and only a trend toward a difference in step time variability ($p=.077$) over the irregular surface. There was, however, a significant difference ($p=.038$) in step time variability in those who were injured in falling when compared to those who fell but were not injured (DeMott, Richardson et al. 2007).

To date, studies that included irregular surface conditions have allowed walking speeds to vary according to subject specific PWS. The omission of a study design that controls both speed and surface leaves a conspicuous void in our understanding of how walking speed, surface, and dynamic stability are related.

DYNAMIC STABILITY MARGINS

A method for quantifying dynamic stability was proposed by Hof et al. (Hof, Gazendam et al. 2005). This method provides a mechanical definition for dynamic stability that is calculated as the dynamic stability margin (DSM). Hof et al. used a modified inverted pendulum model (IPM) of walking to explain DSMs (Hof, Gazendam et al. 2005). Hof et al. defines dynamic stability margins (DSMs) as a velocity adjusted measure of center of mass (extrapolated COM or XcoM) relative to the margins of the BOS. In this model each step represents a new BOS. The equation for DSM is:

$$DSM = (BOS - COM) - (V_o * (h/g)^{1/2}) \qquad \text{Equation 1-1}$$

Where, BOS is the boundary of the base of support[1], COM is the vertical projection of the COM on the ground, V_o is the instantaneous horizontal velocity of the COM in the direction of the BOS boundary (fore-aft or lateral), h is the height of the COM, in the frontal plane 1.34 x leg length from the greater trochanter to the ground in meters, and g

[1] Hof used the center of pressure to define the continuous base of support position.

is the gravitational constant ($9.81\ m/s^2$). The term $(h/g)^{1/2}$ is related to the period of a pendulum and is assumed constant within subjects when using this model. Equation 1-1 can be restated as:

$$DSM = (BOS - (COM + V_o * (h/g)^{1/2})$$ Equation 1-2

Where, $COM + V_o * (h/g)^{1/2}$ is the extrapolated COM (XcoM). This can be simplified to:

$$DSM = BOS - XcoM$$ Equation 1-3

The DSMs are calculated for each step as a measure of the minimum distance between the extrapolated COM (XcoM) and the boundary of the BOS in the frontal plane (BOS_z-$XcoM_z$)[2]. From a strictly mechanical standpoint, a larger DSM represents a greater capacity to resist a perturbation. The greater the DSM, the larger the impulse required to move the XcoM outside of the BOS. Conversely, a smaller DSM is considered less stable (Hof, Gazendam et al. 2005). The minimum DSM typically occurs shortly after initial contact as weight is being transferred to the leading foot during walking[3].

Based on limited research, it is not clear, however, how frontal plane DSMs are related to global stability (i.e. how DSMs might be used to identify fall risk). Results of a single study involving patients with unilateral trans-femoral amputations did not match expectations (Hof, van Bockel et al. 2007). Hof et al. evaluated average frontal plane DSMs during treadmill walking in subjects with unilateral trans-femoral amputations and in age-matched control subjects. This study determined that patients had greater average frontal plane DSMs on the involved sides than either matched control subjects or on the uninvolved sides (Hof, van Bockel et al. 2007). Of interest, the increase in DSMs was contrary to expectations that patients having a greater fall risk would have smaller DSMs.

[2] For this study ISB coordinates will be used.

[3] For brevity sake, DSM means minimum DSM from here on.

Hof argued that the larger DSMs that were observed on the involved side were, "a sensible adaptation to a one-sided impairment" (Hof, van Bockel et al. 2007). Although this may be true, it does not satisfy the assumption that those at risk for falling are less dynamically stable.

The fact that DSMs are based on a strictly mechanical definition of stability without concern for physical capacity represents a flaw in Hof's theory for bipedal walking. This limitation in Hof's theory is exposed when thinking of the ability of an individual to adjust the internal impulses or joint moments in response to a perturbation. Hof's assumption regarding the impulse required to move the extrapolated COM outside of the BOS does not take into account the neuromuscular response that may be quite different from side-to-side in patients with unilateral deficits. In other words, a larger DSM does not necessarily measure the ability to resist a perturbation.

Alternatively, an increase in DSM may be indicative of the real or perceived need to adapt to a perturbation. As such, a healthy adult is expected to possess a markedly different set of responses to a wide range of perturbations than an adult with a LLA. This difference can be attributed to the absence of normal sensory input, reflexes, strength, and balance in subjects with LLA (Winter and Sienko 1988; Scott and Winter 1993)**.** This may also be related to decreased reaction times and degrees of freedom that are observed in patient populations as they develop response strategies to perturbations (Winter and Eng 1995; Rietdyk, Patla et al. 1999; Hofstad, van der Linde et al. 2006; Mackey and Robinovitch 2006). At this point, it is premature to assess fall risk before establishing a stronger basis for Hof's theory. We need to know more about DSMs before we can use them to predict dynamic stability or fall risk.

To resolve the inconsistency between the current theory and results, a modification to Hof's theory is suggested here. In this modified theory, a significant difference in average frontal plane DSMs, above or below normal, is interpreted as a reflection of an inability to adapt normally to a perturbation. This assumes that for a given surface condition and equivalent walking speed, a normal range of DSMs represents the normal ability to adapt to perturbations. Normative values for DSMs in young healthy adults have not previously been published. This study provides an opportunity to establish normal values in our laboratory.

If a smaller average DSM is not related to a destabilizing surface or subjects with obvious impairments, then Hof's original theory must be modified to account for this. Likewise, if average DSMs are larger on the involved side compared to the uninvolved side in subjects with LLA, it brings into question Hof's assumption that smaller DSMs represent greater fall risk.

PURPOSE

Quantification of dynamic stability is instrumental in guiding future standards of evaluation, prosthetic design, and treatment protocols. Our study provides normative data for the quantitative assessment of frontal plane DSMs while controlling speeds over a flat level surface (FLS) and an uneven rocky surface (URS). Young adults with traumatic TTA will benefit directly from this investigation.

RESEARCH AIMS/HYPOTHESES:

Study 1 (Young Healthy Adults)

Aim: To determine the effects of walking speed and surface on average minimum frontal plane dynamic stability margins (DSM) in healthy subjects.

The gravel surface in this study represented a destabilizing and unpredictable challenge to balance control.

Hypothesis 1: Average minimal dynamic stability margins will be greater when walking over the gravel surface at any given speed in young healthy adults (main effect for surface).

<u>Study 2</u> (Adults with Traumatic Trans-Tibial Amputations)

Aim: To determine the effects of surface and walking speed on average minimum frontal plane dynamic stability margins in young adults with lower limb amputations.

<u>Hypothesis 1:</u> Average minimal DSMs will be greater when walking over the gravel surface at any given speed in young adults with TTA (main effect for surface).

<u>Hypothesis 2:</u> Average minimal DSMs will be greater on the involved side when compared to the uninvolved side (main effect for side).

<u>Hypothesis 3:</u> Average minimal DSMs will increase as walking speed increases in young adults with TTA (main effect for speed).

SUMMARY OF DEPENDENT VARIABLES

Dynamic stability margins have been proposed as a measure of dynamic stability in walking that are analogous to the currently accepted method for quantifying standing or static stability in humans. Relating COM control to step placement is both intuitive and quantifiable. In the global coordinate system of a gait lab the BOS-COM horizontal distance represents a measure of functional step width. The addition of COM velocity, normalized to leg length, made DSMs a more precise measure of how step placement controls the COM than static methods used to quantify standing stability (Pai and Patton 1997). Minimum DSMs typically occurred within 100 milliseconds of initial foot contact for each step. Shortly after initial contact, at the beginning of single support phase, the COM position and velocity reversed direction toward the swing leg side.

SIGNIFICANCE OF STUDIES

As a result of their youth, high level of pre-morbid activity, and high expectations, Military Amputee Care Center Program patients participate in activities that are more demanding than those engaged in by the general population with TTA. These demanding endeavors place them at greater risk for falling and causing further injury. Collecting and analyzing normative data in healthy subjects and in high functioning patients with TTAs is an important first step in developing applications for DSMs as an outcome variable.

Patients with TTA have an index to gauge progress that is based on a young person with a TTA instead of an unrealistic comparison with a healthy population.

These studies are the first systematic quantitative assessment of the effects of speed and walking surface on measures of DSMs in service members with and without traumatic TTA. It is a benefit to society as a whole to provide injured service members with the highest level of function possible in the least time. This investigation was relevant to the Military Amputee Research Program (MARP) objectives. The information obtained from this study will potentially benefit all young adults who have TTA as a result of trauma, tumor, vascular disease, or infection.

ASSUMPTIONS

The inverted pendulum model for quantifying dynamic stability margins (DSMs) assumes a constant leg length and negligible angular accelerations of the trunk (Townsend 1985; MacKinnon and Winter 1993). These are well-established limitations of this model but have a negligible affect on the dependent variables in this study (Zijlstra and Hof 1997; Hof, Gazendam et al. 2005; Hof, van Bockel et al. 2007). Based on our observations, DSMs are not very sensitive (±4 cm) to errors in either leg length or COM vertical position. We will account for COM position and velocity in the frontal plane with a 15-segment model (feet, shanks, thighs, pelvis, trunk, head, arms, forearms, and hands).

We defined the boundaries of the BOS in the frontal plane to be the 5th metatarsal heads. In a previous study by MacLellan and Patla the ankle lateral malleolli were used to estimate DSMs (MacLellan and Patla 2006). Hof originally described the BOS as the COP (Hof, Gazendam et al. 2005). In our analysis the 5th metatarsal is an indication of the absolute margin of stability. Because of this assumption we are able to define DSMs in a terrain pit where reliable COP data are unattainable.

LIMITATIONS

1. Due to the nature of traumatic injuries, group homogeneity was not assumed. Time in prosthesis may also be different across subjects. Analyses of covariance were performed

for residual limb length and time in prosthesis. Exclusion criteria helped to control for significant differences and confounding variables (e.g. low back pain, functional limitations, other injuries).

2. We used a gravel pit to represent a destabilizing surface. In other studies a "compliant" foam surface or a firm surface with random obstacles was used to challenge balance control. A foam surface may be a better theoretical control of the surface condition due to its consistent coefficient of restitution, but it is rarely encountered in real life. The gravel surface that we chose is similar to gravel used by Army engineers when constructing base-camps. Because some of our subjects with LLA have a goal of returning to active duty, this surface provided a realistic challenge for them.

3. The use of the 5th metatarsal as an absolute measure of lateral stability is less accurate in the terrain pit due to the random nature of the support surface. This will result in an over-estimation of the average DSM. This effect was similar for all subjects in both studies and is considered in the discussion of results.

4. The centers of mass (COM) for amputee residual limbs and multi-segment prosthetics were estimated, as were the intact limbs, based on cadaver studies. This is a limitation that this type of modeling places on these types of biomechanical studies.

5. In order to calculate variability, more than one trial was collected for each condition. Although some authors have argued that at least 400 steps are needed to get a good estimate of variability, others have indicated that a few steps are enough (Smith 1993; Owings and Grabiner 2003). Due to the nature of this study and the concern for minimizing fatigue in a patient population, we collected two sets of five trials. Each trial included 2-3 steps on each side, so there was the potential to collect 20-30 steps per side for each condition. Although an arbitrary goal of 20 steps per side was set for data analysis, fewer trials were adequate for statistical purposes. In order to test this theory, random sampling was conducted from conditions that had 30 or more trials. Repeated statistical analysis determined that 11 steps yielded a similar result as that obtained from 30 steps for these data.

6. This study was conducted in a clinical setting and there was concern for the over-sampling of the patient population. Due to this concern a single data collection session was conducted without follow-up. Repeated measures were performed within the single session however.

7. The active duty service member does not fit the typical profile of an elderly inactive person with an amputation due to the complications of vascular disease. This limits the generalize-ability of the study results, but also provided comparisons based on loss of limb that could not be found by making comparisons to peers without amputations. Patients with vascular deficits who have rehabilitation potential may indirectly benefit from the example given by the more fit younger person with amputation.

8. The ultimate goal of this research was to improve our understanding of dynamic stability. The ultimate test of this is a prospective study design that tracks subjects over time for falling in order to relate data to fall prediction. Time constraints did not allow a prospective study design. In our amputee population most subjects have experienced at least one fall, usually early in rehab, but many have not (including one Marine with bilateral trans-femoral amputations).

DELIMITATIONS

Males between the ages of 18-35 years old represent the vast majority of patients with LLA. Subjects had to demonstrate independence in all aspects of the locomotor capabilities index-5 (LCI-5; Appendix A). All subjects also had to be at least K3 on the Centers of Medicare and Medicaid Services (CMS) Lower Extremity Functional Levels scale.

> **(K3)** *the ability or potential for ambulation with variable cadence - a typical community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.*

II. RELATED LITERATURE

Introduction

In order to reasonably justify the study of dynamic stability during human locomotion the following pre-conditions were identified: 1) an **application or need** for this knowledge must be found, 2) a sample group must be available and willing to participate in the study, 3) a conceptually valid **model** should be utilized, 4) **independent and dependent variables** must be identified and justified and, 5) the **methods used to measure or quantify dynamic stability** during walking must be valid and reliable. In a review of the literature all five of the stated requirements were found and the timing for this research is favorable.

NEED FOR MEASUREMENT OF DYNAMIC STABILITY IN PATIENTS WITH LLA

Approximately 70,000 vascular related lower limb amputations (LLAs) are performed each year in the United States. An additional 3,000 LLAs are the result of trauma (Dillingham, Pezzin et al. 1998). In the general population, four out of every five traumatic amputations occur in males between the ages of 15 and 30 (Dillingham, Pezzin et al. 1998). Individual medical costs related to LLA can easily exceed $500,000 over a lifetime (MacKenzie, Jones et al. 2007).

One major consequence of LLA is an increased risk of falling (Miller, Speechley et al. 2001). Overall, in the United States, falls account for 500,000 hospitalizations and 1.8 million emergency room visits per year (Thurman, Stevens et al. 2008). Falling in patients with LLA can lead to complications that range from loss of confidence, to fracture, to death (Gooday and Hunter 2004). Falls also increase the cost of rehabilitation by prolonging hospital stays and treatment duration (Tinetti and Williams 1997).

Identifying patients with increased risk of falling is a topic that has received considerable attention in several patient categories including stroke, Parkinson's disease, Alzheimer's disease, multiple sclerosis, osteoporosis, frail elderly, peripheral neuropathy, and lower limb amputation (Boulgarides, McGinty et al. 2003; Robinson, Dennison et al. 2005; Finlayson, Peterson et al. 2006; Tinetti, Gordon et al. 2006; DeMott, Richardson et al. 2007; Thurman, Stevens et al. 2008). Identification of increased fall risk leads to targeted interventions, such as specific strength training, balance training, assistive device prescription, and home health care for those who need them most (Tinetti, Baker et al. 1993; Moirenfeld, Ayalon et al. 2000).

Lateral falls are especially dangerous because of their strong association with hip fractures (Parkkari, Kannus et al. 1999). Winter and Eng (1995) demonstrated that the hip abductors provide the majority of the force for frontal plane balance control in unimpaired walking. Hip motor control in the frontal plane is normally coupled with ankle strength to fine tune center of pressure position with active ankle inversion/eversion (Winter 1995). In subjects with LLA there is not a true ankle joint moment in the frontal plane. In the absence of fine-tuning the margin of error associated with foot placement is reduced. This also places an extra burden on the proximal muscles, including the hip abductors and lateral stabilizers of the spine, to maintain frontal plane balance in walking. Viton (2000) observed co-activation in the gluteus medius and the tensor fascia lata (TFL) in subjects with unilateral trans-tibial amputations when going from double support to single leg support in standing (Viton, Mouchnino et al. 2000). There was no TFL co-activation in the control subjects while doing the same task.

In spite of the importance of falls prevention with patient populations and the need to identify individual risk, there is not a strong consistency between clinical measures and circumstances leading to falls (Boulgarides, McGinty et al. 2003). A look at one high risk for falls population, community dwelling elderly adults, illustrates this disparity. The majority of falls in elderly adults occur during walking (Niino, Tsuzuku et al. 2000), however, current clinical measures are correlated to static measures of instability, static postural sway, or offer no mechanism for the increased risk (Berg, Wood-Dauphinee et al. 1992; Di Fabio and Seay 1997; Dingwell and Marin 2006). This inconsistency between measurement and mechanism may explain why current clinical assessment tools are only fair predictors of falls during walking in elderly community dwellers (Boulgarides, McGinty et al. 2003). It is well established that whole body dynamic activities such as walking are associated with the vast majority of falls (Tinetti, McAvay et al. 1996; Niino, Kozakai et al. 2003). However, clinical assessments for predicting fall risk are based primarily on static stability tests (e.g. single leg balance) or diagnostic functional tests (e.g. the Timed Up and Go) in frail elderly patients (Boulgarides, McGinty et al. 2003). This raises concern regarding the external validity of these measures as predictors of fall risk, under dynamic conditions, in more active populations who are at elevated risk for falling (Overstall, Exton-Smith et al. 1977; Niino, Tsuzuku et al. 2000; Boulgarides, McGinty et al. 2003; Niino, Kozakai et al. 2003). For example, many independent living elderly adults and younger adults with LLA score well on tests that have been validated on elderly frail adults, yet still experience an elevated rate of falling (Riddle and Stratford 1999; Boulgarides, McGinty et al. 2003; Gauthier-Gagnon and Grise 2006). This ceiling effect indicates that there is a more rigorous requirement for the evaluation of higher functioning individuals who are prospectively at risk for falls.

Identifying Patients Who Will Benefit From Study Of Dynamic Stability

Lower limb amputations (LLA) can be broadly categorized into *traumatic* and non-traumatic etiologies. The vast majority of LLAs are non-traumatic and due to vascular disease or diabetes in an elderly population (Dillingham, Pezzin et al. 1998). Traumatic amputations generally occur in a younger, mostly male, population. Four of every five traumatic amputation occur in males, most between the ages of 15 and 30 (Dillingham, Pezzin et al. 1998). In this population, level of injury, time since injury, multiple stump or prosthetic problems, and fear of falling are correlated to risk of falling (Miller, Speechley et al. 2001).

Young service members with lower limb amputations (LLA) represent a group that is capable and motivated to participate in gait studies. The military performance laboratory at Center for the Intrepid (Fort Sam Houston, San Antonio, Texas) was designed specifically for human performance testing and rehabilitation. The Global War on Terror (GWOT) has resulted in over 400 American service members with traumatic LLA. Most experience falls early in rehabilitation or when transitioning from one level of rehabilitation to a higher level (personal communication with staff of CFI). Balance assessments that are used to predict fall risk in a sedentary older population with LLA have proven to be of little use in a motivated younger active population (personal communication with staff of CFI).

Young active patients with isolated trans-tibial amputations (TTAs) have excellent rehabilitation potential. Excellent rehabilitation potential does not always translate to abatement of fall risk however. Time in prosthesis, length of residual limb, fear of falling, back and limb pain, residual limb problems, and presence of concomitant injury are related to fall risk in patients with LLAs (Isakov, Burger et al. 1996; Miller, Speechley et al. 2001). In spite of the complex set of challenges, the isolated effects due to LLA are probably best determined in a young population (compared to frail elderly subjects with multiple pathologies and age related physiological changes).

One recent meta-analysis reviewed 48 studies that dealt with functional capacity (aerobic capacity, anaerobic capacity, muscle force, flexibility, and balance) and walking ability (walking velocity and symmetry) in patients with LLA (van Velzen, van Bennekom et al. 2006). In this review a consistent decrement was noted in balance and muscle strength as a result of amputation. A strong relationship was also noted between balance and walking ability. In discussions with physical therapy and research staff at the Center for the Intrepid it is clear that young motivated service members, who are anxious to overcome the loss of a limb, or limbs, often fall, either due to their exuberance to achieve independence or because they over estimate their current abilities.

The "Inverted Pendulum" Model

In human walking "instability" occurs just prior to every step. Stability is re-established with each step by placing the foot beyond the extrapolated COM (XcoM) in the direction of travel. In the mechanical description of standing balance an inverted pendulum model is often used to illustrate the relationship between center of mass

(COM) and base of support (BOS) (Figure 1). Traditionally, if the vertical projection of the body's COM exceeds the boundaries of the BOS, then the system becomes unstable and a step must occur to prevent a fall (Duncan, Weiner et al. 1990; King, Judge et al. 1994). More recently it has been established that if the COM is outside of the BOS, but the velocity of the center of mass is in the direction of the BOS the system may still be dynamically stable (Pai and Patton 1997).

This is what happens during stepping as long as the combination of COM position and velocity are within a feasible state space region. Falls forward can still take place if the upper boundary of this region is exceeded and falls backward would take place if the lower boundary is not exceeded. A single point within the BOS acts as the origin for the force vector that directs the balance response to changes in the COM position and velocity and is called the center of pressure (COP). Winter describes the COP as, "the neuromuscular response to imbalances of the body's center of mass" (Winter 2005). If the COM position and velocity is beyond the BOS then the COP can no longer redirect the COM over the BOS and instead serves to push the COM farther away from the BOS (Pai and Patton 1997). By stepping ahead of the velocity adjusted COM it is possible to recapture the COM within a new BOS. The fact that the COM must move outside of the BOS during walking must take place has, until recently, limited the proper application of an inverted pendulum model when quantifying dynamic stability (Pai and Patton 1997; Iqbal and Pai 2000). In the last few years a new approach to measuring dynamic stability during human locomotion, within the context of the inverted pendulum model and an "extrapolated COM", has been proposed and tested (Hof, Gazendam et al. 2005; Hof, van Bockel et al. 2007). The result of this development

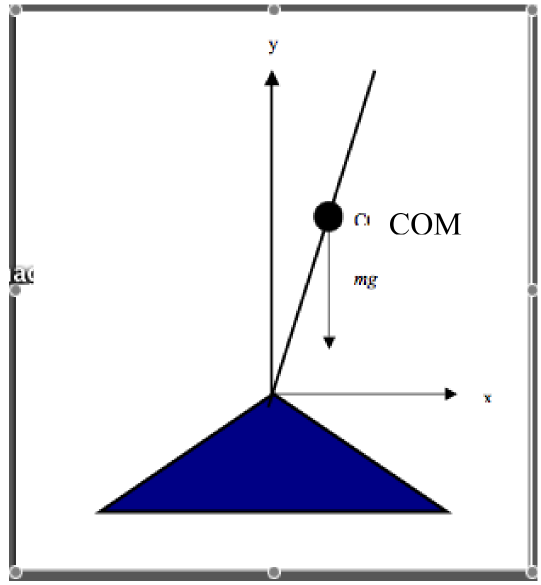

Figure 1-1: Inverted pendulum model

is the dynamic stability margin (DSM), which is used to quantify the mechanical properties of dynamic stability (Hof, Gazendam et al. 2005).

The direction and magnitude of walking velocity is primarily forward, but there is a small lateral component as well. The lateral components of walking velocity, the relatively narrow width of gait, and a limited lateral base of support are reasons for concern over lateral falls. The significance of lateral falls is that in elderly patients lateral fallers have a 4-6 times greater risk of hip fractures than anterior or posterior fallers (Greenspan, Myers et al. 1998). Another reason that anterior and posterior measures of stability are considered with less apprehension is that high variability of kinematic and stability measures in the sagittal plane are common in both normal and pathological gait, while the frontal plane tends to be less variable (King, Judge et al. 1994; Dingwell, Ulbrecht et al. 1999; Hof, van Bockel et al. 2007). This may indicate a relative importance that higher motor control centers place on maintaining lateral stability through a stepping strategy foot placement (Hemami, Barin et al. 2004; Bhatt, Wening et al. 2006; Hof, van Bockel et al. 2007).

Independent Variables: Identification and Justification

Speed and Surface in Human Locomotion

Speed *and* surface conditions are important factors to consider when using any measure of dynamic stability. Several studies aimed at quantifying dynamic stability at controlled speeds over level ground or during treadmill walking have not included changes in surface conditions (Cappozzo, Figura et al. 1982; Minetti, Capelli et al. 1995; Titianova and Tarkka 1995; Donker, Mulder et al. 2002; McNeill Alexander 2002; Kubo, Wagenaar et al. 2004; Dingwell and Marin 2006; England and Granata 2006; Orendurff, Segal et al. 2006; Hof, van Bockel et al. 2007). Likewise, there are many examples of studies that evaluated effects due to surface but did not control for walking speed. When studies have included uneven surface conditions, the dependent measures generally include changes in preferred walking speed (PWS), temporal and spatial variability, and metabolic cost due to surface conditions (Marigold and Patla 2002; Menz, Lord et al.

2003; Menz, Lord et al. 2003; Menz, Lord et al. 2003; Richardson, Thies et al. 2004a; Thies, Richardson et al. 2005a; Thies, Richardson et al. 2005b; MacLellan and Patla 2006). We used a novel walking protocol that controlled walking speeds over two surface conditions to gain a better understanding of how these independent variables affected DSMs.

Speed[4]

Controlling for speed of walking has been used to demonstrate normal changes in stride variability and local stability over a range of speeds from very slow, to normal, to very fast using a treadmill (Dingwell and Marin 2006). Speed appears to be a control parameter for strides temporal and spatial variability as well as for local stability. In other words, as speed changes so do these variables. The way that these variables respond to changes in walking speed do not lead to consistent conclusions however. Variability increases at slower walking speeds indicating instability, but local stability increases at slower speeds, indicating increased stability (England and Granata 2006). Only one study addressed the direct measure of dynamic stability at varying speeds in an amputee population (Hof, van Bockel et al. 2007). The results of this study indicate that dynamic stability margins increase as speed increases in normal subjects as well as in those with trans-femoral amputations. The effects of speed were more profound on the DSMs of the amputation side. This is presumably due to the lack of proprioception and the inability to adapt to foot placement errors with an ankle roll off. Hof et al. concluded that increased stability might be preferable to step symmetry in this population (Hof, van Bockel et al. 2007). This conclusion makes two assumptions that may be contentious. The first is that you must sacrifice symmetry to gain stability; the second assumption is that an increased dynamic stability margin is equivalent to increased dynamic stability in this population (Hof, van Bockel et al. 2007). Nolan (2003) demonstrated that temporal asymmetry decreased but loading asymmetry increased at increased walking speed in active above-knee and below-knee amputees (Nolan, Wit et al.).

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[4] For reporting purposes speed is usually normalized to leg length, height, preferred walking speed, or a non-dimensional Froude number to account for between subjects differences in size.

Surface

The use of compliant and uneven walking surfaces to simulate sensory challenge and to differentiate normal from abnormal movement response is found often in recent literature (Menz, Lord et al. 2003; Menz, Lord et al. 2004; Richardson, Thies et al. 2004b; Thies, Richardson et al. 2005a; Thies, Richardson et al. 2005b). While speed might be an important control parameter, uneven surfaces may pose a greater challenge to the dynamic stability of those with LLA. This increased challenge to stability is a reflection of loses in sensory feedback, reflexive muscle action, motor control, and a change in normal reaction forces resulting from a change in surface (Marigold and Patla 2005). Some evidence also exists that muscle response is pre-programmed for normal surfaces and stepping on to and off of compliant surfaces requires an adjustment to the muscle response that is seen during recovery steps (Marigold and Patla 2005). One study addressed compliant surface and dynamic stability in a normal population, but did not control for speed (MacLellan and Patla 2006). Diminished lighting had no effect in a study conducted by Thies (2005) that compared young and old healthy women on even and uneven surfaces (Thies, Richardson et al.).

Speed and Surface Interactions

Interactions between walking speed and uneven surfaces are not well understood. Studies indicate that gait becomes generally more variable on a compliant surface (Marigold and Patla 2005) variability. Head stability appears to be a major objective of motor control system on uneven surface (Menz, Lord et al. 2003). Dynamic stability margin using COM was significantly different in the compliant surface condition in one study (MacLellan and Patla 2006). This increase in stability was achieved by taking wider and longer steps while on the compliant surface. The ability to increase the base of support in response to a surface change is a critical and time sensitive indicator of stability.

Studies have been conducted using compliant surfaces at preferred speeds in elderly subjects and while controlling for speed in a young subjects (Menz, Lord et al. 2004; Richardson, Thies et al. 2004a; Thies, Richardson et al. 2005a). The results of these studies indicated that head alignment is maintained by increasing variability on an uneven surface. Age is associated with increased variability and decreasing speed on an uneven surface (ref).

Dependent Variable: Identification and Justification

Dynamic Stability Margins

Dynamical systems are quantified in the fields of engineering, physics, and chemistry. Efforts to quantify and study dynamic stability in human walking have increased in recent years (Hurmuzlu and Basdogan 1994; Hurmuzlu, Basdogan et al. 1996; Dingwell, Cusumano et al. 2000; Pai, Maki et al. 2000; Dingwell, Cusumano et al. 2001; Marigold and Patla 2002; Patla 2003; Hemami, Barin et al. 2004; Hof, Gazendam et al. 2005; Oates, Patla et al. 2005; Dingwell and Marin 2006; England and Granata 2006; MacLellan and Patla 2006; Hof, van Bockel et al. 2007). Although static measures of stability are still valuable and correlate to fall risk in those with static instability, they have limitations when it comes to locomotion. In order to best measure stability during human movement a progression from static stability measures to dynamic stability is inevitable. This is not a simple process however, which is made abundantly clear by the fact that it has taken more than a decade to go from conception to controversy. Measures of dynamic stability in this proposal can be traced to two authors and generally digress along two paths. One path is set in fundamental engineering principles and the second is based on an extrapolation of static stability measurement of COM using an inverted pendulum model as a starting point. The methods and theories behind dynamic stability measurements are summarized below.

Quantifying Dynamic Stability Margins

In 1997 Pai wrote a paper on center of mass velocity-position predictions for balance control (Pai and Patton). In this and in a later paper an important limitation to using the inverted pendulum model in dynamic situations was exposed and a modification was suggested (Pai, Maki et al. 2000). The models of the time did not take into account the direction and magnitude of the COM velocity when predicting stability. Because the very nature of walking requires a change in position, the inverted pendulum will predict instability with every step. A modification to the inverted pendulum model was suggested that adds COM velocity to its position and relates this to the base of support for stability calculations. Stability can then be measured as the success or failure of a stepping strategy to maintain this "extrapolated COM" (XcoM) within the base of support. Hof (2005) derived the necessary equations to justify this new model and has tested it on normal subjects and in subjects with trans-femoral amputations. The extrapolated COM (XcoM) measures of dynamic stability thus far indicate that COM alone tends to over-estimate dynamic stability. It is also observed that the minimum dynamic stability margin occurs shortly after heel strike on the lead foot during walking. In normal subjects and on the uninvolved limbs of subjects with LLA ankle muscle action appears to be responsible for fine tuning the COP after heel strike. The involved side in subjects with LLA lacks this adaptability (Hof, van Bockel et al.).

Two methods are described for locating whole body COM used to calculate dynamic stability margins. In one, instantaneous center off mass position is calculated using force plate center or pressure (COP) data (Zatsiorsky and King 1998). From the COM position data the instantaneous velocity is calculated as the first numerical derivative. This method requires a force plate or force plate instrumented treadmill in order to make the calculations. An alternate method for estimating instantaneous position of the COM is to use the sum of the COM of the body segments.

MacLellan quantified dynamic stability margins using segmental analysis and 23 markers to estimate COM dynamic stability (MacLellan and Patla 2006). MacLellan (2006) also used a marker on the lateral malleolus to estimate lateral stability margin and reported similar results as Hof (2005) did using COP readings (MacLellan and Patla) .

Measurements of dynamic stability margin, assume an inverted pendulum model. Hof (2005) derived the necessary equations to quantify an "extrapolated COM" in walking by adding the position of the body's COM vertical projection on the ground and the product of the velocity of the COM and a pendulum constant: the square root of COM height from the ground divided by gravity. The difference between this extrapolated center of mass (XcoM) and the shortest distance to the edge of the lead foot in walking (i.e. the extreme COP) is defined as the dynamical stability margin (DSM). This can be measured in the anterior to posterior (AP) direction or the medial to lateral (ML) direction. The equations for DSM in the ML direction are listed below:

$$DSM = COPz - (COMz + Vz \bullet \sqrt{l/g}\ ) \qquad \text{Equation 2-1}$$

$$XcoM = (COMz + Vz \bullet \sqrt{l/g}) \qquad \text{Equation 2-2}$$

$$DSM = COPz - XcoM \qquad \text{Equation 2-3}$$

Where COPz is the ML location of the COP in the frontal plane, COMz is the ML location of the COM in the frontal plane, Vz is the ML velocity of the COM in the frontal plane, and is the constant period of an inverted pendulum, the square root of leg length (l) divided by gravity (g). The right side of equation 2-1 can be combined to create a new term that is referred to as the XcoM (Equation 2-2). Equation 2-3 is the condensed form of equations 2-1 and 2-2. For time series analysis the DSM is measured starting at heel strike of the lead foot and ending at toe off of the ipsilateral foot.

This approach allows for foot placement of the leading leg to re-establish a potentially stable base of support and it includes velocity of COM as an important element in dynamic stability margin calculations. These assumptions allow for a definition of dynamic stability that tolerates stepping as an acceptable response to COM displacement and velocity. It is important to acknowledge that the stepping response is not always effective and can lead to greater instability or falls on subsequent steps (Pai, Rogers et al. 1998).

This approach to quantifying dynamic stability in walking has yet to be fully explored. Early work indicates that it is valid and reliable at measuring margins of stability, time to margin of stability, and even at predicting step placement in normal subjects (Hof, Gazendam et al. 2005; Hof, van Bockel et al. 2007). One study estimated lateral stability by using markers on the lateral malleolus during walking over level ground and on a cushioned surface in normal adult subjects (MacLellan and Patla 2006). The results of using a single marker as an estimate of COP were similar to those obtained when direct measures of COP where used to determine the dynamic stability margins over level ground (Hof, Gazendam et al. 2005; MacLellan and Patla 2006). These findings indicate that dynamic stability has been over-estimated in the past because the velocity of the COM was not included in calculations of COM to COP distance. Dynamic stability margins increased when walking on a compliant surface at a self-selected uncontrolled speed (MacLellan and Patla 2006). Another study evaluated subjects with transfemoral amputations and matched controls at three speeds (Hof, van Bockel et al. 2007). This study demonstrated that DSM increased as speed increased in normal subjects and in subjects with transfemoral amputations. However, the involved lower extremity exhibited a substantially greater DSM in response to speed than did the uninvolved side. The uninvolved side reacted similarly to the normal subjects as speed changed (Hof, van Bockel et al. 2007).

Recently, Mademli (2008) expanded on Hof's work in the sagittal plane by testing 11 young and older male adults on recovery from a forward fall before and after a fatiguing task. Although there was a difference in DSMs due to age, young had larger DSMs, the fatiguing task did not result in a change in DSMs. An increase in the knee flexion angle for both groups after fatigue appeared to be responsible for the maintenance of the DSMs. Mademli concluded that the tendency for DSMs to be invariant in normal subjects points to a higher central nervous system control mechanism that is able to rapidly adapt the motor response in order to maintain dynamic stability. In the sagittal plane the inverted pendulum model appears to be correct in predicting a larger DSM in a stronger, theoretically, more dynamically stable population (Mademli, Arampatzis et al. 2008).

SUMMARY

The quantitative analysis of dynamic stability in human walking has yet to be explored and exploited to its full potential. Through a series of studies it is hoped that results will support the view that dynamic stability measures offer something beyond what is currently available and that these measures are not limited to research applications. Young Service members with LLA represent a patient population that is generally ready and willing to participate and has the physical and mental faculties required to complete a fairly rigorous walking protocol. The assumption of an inverted pendulum model with extrapolated COM (XcoM) to measure dynamic stability margins is somewhat intuitive and easy to understand, while Floquet theory offers an alternate method based on periodic, non-linear oscillating, systems. Independent and dependent variables selected for this study are consistently used in gait studies and will be recognizable to researchers and clinicians that specialize in gait disorders.

The current review represents a small body of work in this area and the interpretation of results from these studies are not conclusive about how and why these measures may be used to improve the condition of patient populations who have obvious or subtle instability with gait. Furthermore, it is not clear that increasing the stability margin is a sign of a stable system. In contrast, a larger margin of stability may be a warning sign of pending or current instability or fear of falling.

In order for these measures to transcend the realm of scientific experimentation into the area of clinical applications it will require further study and a similar process that was undertaken in the 1970s and 1980s to develop normative values of static or standing stability (Nashner 1976; Overstall, Exton-Smith et al. 1977; Woollacott, Shumway-Cook et al. 1986; Nashner, Shupert et al. 1989; Nashner and Peters 1990; Wolfson, Whipple et al. 1992; Wolfson, Whipple et al. 1994; Nichols, Glenn et al. 1995; Winter, Prince et al.

1996; Nichols 1997). Without normative ranges of data at a variety of speeds and surface conditions, it is not prudent to speculate at the significance of these measures. The ultimate goal of this area of study, beyond this proposal, is to discriminate abnormal from normal stepping responses to perturbations.

III. RESEARCH METHODS

Study 1: The Effects of Walking Speed and an Uneven Rocky Surface on Dynamic Stability Margins in Healthy Young Adults

INTRODUCTION

The ability to adapt center of mass control to a wide range of walking surfaces and speeds during locomotion represents a desirable level of function. The use of DSMs to quantify this control has recently been described (Hof, Gazendam et al. 2005). However, normal values for frontal plane DSMs have not been reported to date. We collected data from 22 healthy young adult service members stationed at Fort Sam Houston (San Antonio, Texas) and 22 young adults with unilateral traumatic LLA. Studies conducted in unimpaired subjects and in subjects with known fall risk will improve the ability to characterize DSMs.

RECRUITMENT AND SCREENING OF SUBJECTS

Military trainees at Ft. Sam Houston, TX were recruited for participation in an experimental protocol that required approximately 2 hours and ½ mile of walking. Volunteers were screened for inclusion based on age (between 18-35 years) and achieving a passing grade on a current Army Physical Fitness Test (APFT) within the last 6 months. Exclusion criteria included a history of orthopedic injury or neurological injury or major trauma or surgery to the lower extremities that could have affected normal walking, back pain, or physical limitations. For female volunteers, pregnancy was also an exclusionary condition. When all inclusion/exclusion criteria were met, subjects were invited to read and sign a locally approved institutional review board (IRB)[5] consent form and a health insurance portability and accountability act (HIPAA) disclosure form (Appendix A).

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[5] The University of Texas at Austin Office of Research Support and Compliance IRB also approved these documents for these studies.

STUDY DESIGN AND SAMPLE SIZE

A single session repeated measures quasi-experimental design was conducted. Subjects walked over a flat level surface (FLS) and an uneven rocky surface (URS) in sets of five repetitions. Preferred walking speed (PWS) trials were collected at the beginning and end of the walking protocol. Five dimensionless Froude (control) speeds were assigned in pseudo-random order. Speeds were standardized to each subject's leg length, to provide a basis for dynamic comparisons across subjects. Sample size estimation was based on standard deviations reported by Hof (2007), a 2-factor analysis of variance (ANOVA) design, α=0.05, a moderate effect size (0.25), and a desired power of 0.80. From this analysis, a minimum of 15 subjects was recommended. We anticipated that some data might be unusable or lost due to technical difficulties. We also included males and females in this study. For potential comparisons to our patient population, we expected at least 97% males based on reported injury statistics for traumatic amputations in the military; we skewed our recruitment toward male enrollment. The total number recruited for this study of uninjured subjects was set at 22, with a minimum of 15 male subjects. We actually recruited 16 males and 6 females for this study.

EXPERIMENTAL PROTOCOL

On successful completion of initial screening and consent, health history questionnaires were completed and reviewed (Appendix B). This was done in case subjects neglected to include pertinent information during the verbal interview and to provide a written documentation of health status. Subjects were then asked to squat and duck walk for a few paces as a quick screen of lower extremity range of motion and mobility. Subjects were then given up to three attempts to stand on one leg with eyes open for 20 seconds as a quick screen of balance.

All measurements and data collections were conducted while subjects wore their physical training shoes (running shoes). Height and weight were recorded, based on self-reported values. From height and weight values, a body-mass index (BMI; kg/m^2) was calculated for each subject. Military trainees undergo height and weight measurements as part of their frequent fitness testing, so this information was based on recent and recallable information. Shoe widths and lengths were measured at the widest and longest dimensions of the outer soles (bottoms). With the shoe dimensions and the heel and 5^{th} metatarsal marker it is possible to create virtual points to map the feet if additional analysis of this data requires it (e.g. sagittal plane DSMs). Leg lengths were measured using a standard retractable Tailor's tape measure.

Leg length was defined as the distance from the greater trochanter (GT) to the ground using a line that passed through the lateral malleolus. Subjects were instructed to stand normally with feet approximately hip width apart and knees fully extended. Measurements were taken for both sides and repeated if not within ½ centimeter of each other. The GT was defined as the most prominent lateral aspect of the proximal femur to palpation. Measurements were rounded up for Froude number calculations and the longer leg length was used if there is a side-to-side difference after repeated measurements. Leg length differences of up to 2 centimeters are considered to be within normal limits and did not exclude a subject from participation (Gurney 2002).

Froude speeds were used in walking studies to non-dimensionalize walking for the wide range of heights and leg lengths between the subjects (Kram, Domingo et al. 1997; England and Granata 2006). This technique is supported in human and animal studies that show a strong correlation between optimal walking speeds and leg lengths (Alexander 1984). A Froude number of approximately 0.40 coincides with PWS ± 5% in young healthy humans (England and Granata 2006). Table 3-1 lists the five Froude speeds prescribed for this study (self-selected walking is not a control speed). In order to determine the effects due to speed, surface and interactions, the same speeds were used for both surfaces in this study. Froude speeds are based on the following equation:

$$FN = V/(L \cdot g)^{1/2} \quad \text{Equation 3-1}$$

Where FN is the Froude number (0-1), V is walking velocity, L is the leg length from greater trochanter to the floor in meters, and g is the gravitational constant (9.81 m/s^2)

(England and Granata 2006). Algebraic manipulation provided the velocity values for each subject:

$$V = FN * (L \cdot g)^{1/2} \qquad \text{Equation 3-2}$$

Plus and minus 5% of these speeds were entered into Biofeed Trak (Motion Analysis, Santa Rosa, CA) for later use in an audible cueing system that provides real-time feed back of walking velocity.

Table 3-1: Range of normalized (controlled) walking speeds on both surfaces FN=Froude #.

Froude Speed (*based on .40)	**Healthy: Study 1**	**LLA: Study 2**
1	-40% (0.24)	-40% (0.24)
2	-20% (0.32)	-20% (0.32)
3 Index speed*	FN (0.40)	FN (0.40)
4	+20% (0.48)	+20% (0.48)
5	+40% (0.56)	+40% (0.56)

After leg lengths were recorded, 55-lightweight reflective markers (12-25 mm diameter) were affixed to 15 body segments using double-sided adhesive tape and elastic straps. Fifty-two markers were arranged so that four non-collinear markers or rigid marker plates are affixed to 13-segments (feet, shanks, thighs, pelvis (CODA), trunk, head, arms, and forearms). Rigid marker plates were placed over the shanks and thighs to reduce the negative effects of independent skin movement that can result in marker noise (Andriacchi, Alexander et al. 1998). The hands were identified with the two distal forearm markers and a single marker placed over the mid-dorsal surface of the 3rd metacarpal of each hand. Finally, a single marker was placed on the right scapula for side identification. During real-time tracking, the data collection software (EVaRT 5.0.3, Motion Analysis) uses a custom script program to identify right side based on the asymmetrical placement of the scapula marker.

After marker placement, subjects were instructed to stand in the data collection area and assume a standing anatomical position. Static calibration (1 second) and range of motion (200 seconds) trials were collected and reviewed for marker identification in EVaRT post-processing mode. Landmark labels were assigned to the range of motion (ROM) trial using a custom model template in EVaRT. The model template was then extended to provide real-time model reconstruction during subsequent walking trials.

A compressible digitizing wand with four reflective markers was included in the capture area during subject specific calibration trials and compressed during the ROM trial. During a digitizing trial (200 seconds) the tip of the wand was used to create virtual points on the axes of the ankle, knee, hip (greater trochanter), shoulder and elbow joints. A custom script (C-Motion) was used to assign the digitized points when two target markers on the compressible digitizing wand reached a distance threshold, established during the ROM trial (Figure 3-1). The iliac crests were also digitized for potential use in an alternate pelvis model (Helen Hayes). This process accounted for 20 digitized or virtual marker points for a total of 75 real and virtual markers for each subject. Subjects then began the walking protocol.

This study was conducted in conjunction with normative kinematic and kinetic data collection for the MPL gait lab. Although the dependent measures could be derived from kinematic data, kinetic data were also collected from a force platform (FP) instrumented walkway. Subjects were blinded to the use of the FPs so they would not inadvertently try to target their steps within the visible margins of the FPs. For clinical norms, the goal was to collect a minimum of three (3) good FP strikes per side during five (5) walking trials over a level walkway in the military performance lab.

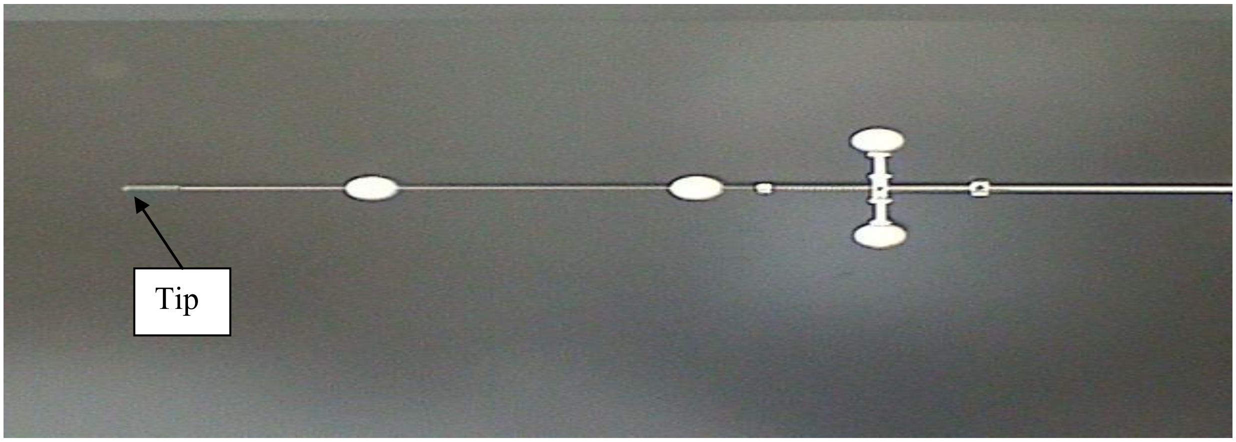

Figure 3-1: Digitizing wand.

Gait Lab Orientation

Prior to beginning the walking protocol, subjects were oriented to the MPL gait lab (Figure 3-2). The key features of the gait lab were data capture areas that included: 1) the middle 1/3 of the 50-foot long main laboratory walkway, with eight in-ground force platforms (AMTI, Watertown, MA), and 2) a parallel 14-foot long by 4-foot wide gravel terrain pit. Each capture area had 15 feet of level surface leading up to either end, this allowed subjects to reach steady speed prior to data collection (Mann, Hagy et al. 1979).

Figure 3-2. Flat level surface (FLS) and uneven rocky surface (URS).

Walking Protocol

Prior to beginning data collection an investigator demonstrated two trials at PWS by walking back and forth over the main walkway. The instructions to the subjects were to, "walk normally at a comfortable pace". Subjects will also be instructed to maintain a normal gaze on the horizon and will be given eye-level target areas to focus on. This was done to promote straight line walking and to standardize head position across subjects. These measures also distracted subjects from targeting their steps on the FPs that were flush with the floor but visibly outlined by spaces between the floor tiles. Subjects were instructed to start each trial by lining up their toes with a moveable indicator on the floor. The starting points were adjusted between trials and speeds to improve the probability of good FP landings.

Speed and surface conditions were grouped into blocks of five trials for each speed/surface combination. For each speed, five good level walking trials werre followed by five good trials over the gravel surface. Because of the destabilizing nature of the gravel, subjects were instructed to self-protect in the event of a stumble or fall, rest breaks were offered as needed, and rest was taken when the gravel surface was re-leveled between trials (as needed). This procedure was repeated for all speeds.

Although the goal was to collect five trials per block, additional trials were conducted if speed ranges were not matched, there was an obvious change in speed from the beginning to the end of a trial, or there were fewer than three good FP events per side over the main walkway. Typically, one investigator activated the data collection cameras and monitor the real-time wire-frame animation model while another investigator recorded good foot strikes over the force platforms.

Although control speeds were systematically ordered, using a pseudo random method, PWS were always the first and last trial condition for each subject. Subjects were allowed several practice trials at PWS to get comfortable with the testing procedures and to warm-up. The practice trials also provided information about step placement on the FPs and allowed investigators to make adjustments to the starting points. Subjects then walked back and forth over the main walkway for five good trials, followed by five good trials back and forth over the gravel surface. Practice was not used prior to the gravel surface conditions to avoid fatigue.

After the initial trials at PWS, controlled speeds were introduced as an investigator described the audible cueing process to the subjects. A loud audible tone sounded when a subject's walking velocity (C7 marker) was within the prescribed speed range (Table 3-1). Subjects were instructed to acquire the target pace prior to entering the capture area and maintain the tone as much as possible while in the capture area. Subjects were discouraged from making large adjustments to speed while in the data capture area. Subjects were then given 3-10 practice trials at prescribed speeds over-ground prior to data collection at the new speed. The practice trials allowed subjects to obtain a consistent tone from the tracking system and also allowed adjustments to the starting points for data collection. On completion of five good trials over-ground, subjects were moved to the walkway leading to the gravel terrain pit. Subjects were instructed to walk at the same controlled speed, just completed over-ground, and to listen for the audible tone for feedback.

Once all speed and surface combinations were collected, a second set of trials was collected to provide additional data. Practice trials were eliminated for the second set to reduce extra time and effort[6]. There are several reasons to do repeated measures; the main reason was to get enough steps to be able to reliably quantify our dependent measures and the variability of those measures.

The design of the walking protocol was also intended to limit other threats to internal consistency in this study, which include: physical or mental fatigue, learning effects, order effects, condition effects, and marker slippage. The walking protocol required at least one-hour to complete and used a relatively novel interactive method to control walking speeds. It also involved a gravel surface that created untested challenges to strength and balance over multiple trials. To minimize mental and physical fatigue, subjects were offered breaks during data collection. Our healthy young adult subjects were all soldiers and all able to pass the APFT, which requires maximum effort for two

[6] Clinical testing indicated that subjects could match the target speeds without additional practice.

minutes each on the push-up and sit-up events, and a two-mile run. They also conduct training over uneven terrains on a daily basis. Effects due to practice or learning were not expected in this population.

To minimize order effects, speeds were assigned in a systematic order. The order of walking speeds for Froude numbers 1-4 were determined using a 1-4 Latin square, which accounts for 24 permutations (Table 3-2). The Froude 5 speed was always assigned as the last control speed for each sequence of walking speeds.

The effect of going from a level surface to a gravel surface and then back to the level surface could have created a condition effect. To limit the condition effects, subjects were allowed to practice walking on the level surface after each set of walking over gravel. The adaptations that occur when going from a level surface to a gravel surface may be of interest, so practice trials were not conducted for level to gravel surface transitions. After both sets of control speeds were completed a final set of PWS trials was conducted in order to provide pre-post protocol comparisons, for descriptive purposes.

During walking trials, if a marker fell off the system did not provide real-time model reconstruction. When real-time tracking failed to reconstruct the model, data collection was paused to check marker placement. If a marker fell off, moved, or a marker plate shifted, a new static trial was conducted to ensure reliability during subsequent trials. For a good trial, prescribed speeds were met on entering the collection areas and maintained within ± 5% during the majority of the trial. Successful steps were based on average values from heel strike on one foot until heel strike on the contralateral side. To ensure inter-session consistency, a data collection checklist was included in each subject folder to ensure that protocol events occured in consistent order (Appendix C). Finally, subjects were given copies of the informed consent and HIPAA disclosure that they signed.

Table 3-2: Subject numbers coincided with order of presentation of walking speeds.

Speed Sequence Assignments

1	2	3	4	5	6
1	1	1	1	1	1
2	3	3	4	4	2
3	2	4	2	3	4
4	4	2	3	2	3
5	5	5	5	5	5
7	8	9	10	11	12
2	2	2	2	2	2
3	3	4	4	1	1
4	1	1	3	3	4
1	4	3	1	4	3
5	5	5	5	5	5
13	14	15	16	17	18
3	3	3	3	3	3
4	4	1	1	2	2
1	2	4	2	4	1
2	1	2	4	1	4
5	5	5	5	5	5
19	20	21	22	23	24
4	4	4	4	4	4
1	1	2	2	3	3
2	3	3	1	1	2
3	2	1	3	3	1
5	5	5	5	5	5

Data Collection

Kinematic data were collected at a sampling rate of 120 Hz, using the 20-camera Eagle infrared digital camera system, (Motion Analysis) mounted around a 2000 sq. ft. gait laboratory (Figure 3-3). The force platforms (FP) in the main walkway collected kinetic data at a sampling rate of 1200 Hz. Laboratory calibrations were done in accordance with the standing operating procedure (SOP) for the Military Performance Lab. The system was consistently calibrated to within 1.0 mm accuracy for marker locations prior to each day of data collection. Calibration included a static L-frame calibration with four reflective markers of known spacing (1 second). The L-frame calibration was also used to define the global coordinate system (GCS) for the gait lab. A dynamic calibration trial was performed by moving a wand with three markers, of known spacing for 200 seconds through the volumes over both walkways and in front of all cameras.

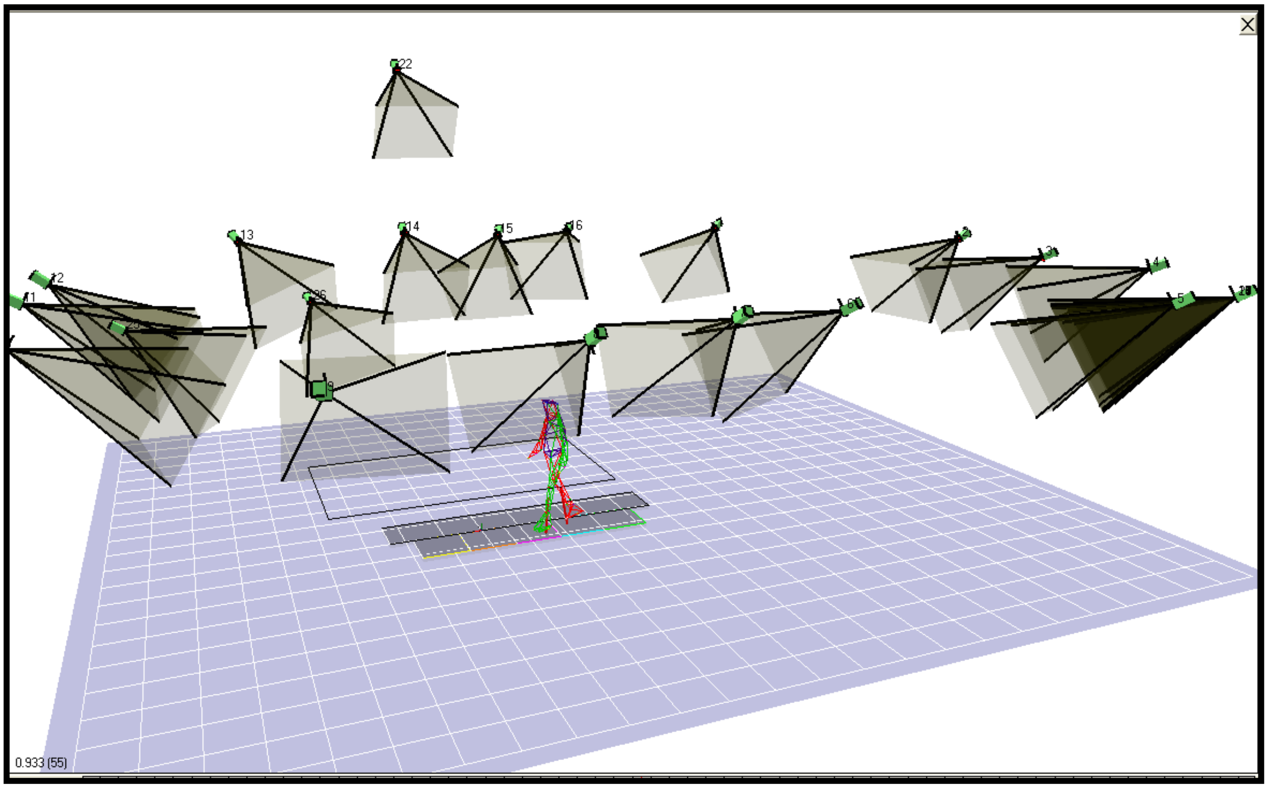

Figure 3-3: The MPL gait lab in EVaRT view with wire-frame model in FLS volume.

DATA PROCESSING

In order to make automatic kinematic calculations based on a model within the Visual 3D software (C-Motion, Inc., Rockville, MD) marker definitions, segment definitions, segment anthropometry, and subject specific data were entered into a custom model template. In order to provide necessary model parameters, a static calibration file was collected and 55-marker locations were labeled according to the template. A subject specific motion file was collected and fit to an algorithm of possible marker movements relative to each other for that subject. This was accomplished through a standing range of motion trial that included standardized movements from all joints in the model.

Marker definitions provided specific information about anatomic landmarks that were used in the segment definitions. Segment definitions were based on marker placement, proximal and distal joint centers, and adjacent segments. Segment anthropometry was based on cadaver studies of mass distribution and geometric modeling (Table 3-3 and Figure 3-4) (Dempster, Gabel et al. 1959; Hanavan 1964). Segments were modeled as geometric shapes, such as cylinders, with proximal and distal joint diameters as input parameters. Each segment also had its own local coordinate system (LCS) based on ISB standards (Wu, Siegler et al. 2002; Wu, van der Helm et al. 2005). The only subject specific metrics for standard kinematic analysis were subject height in meters and mass in kilograms.

Raw data for this study was initially edited in the post-processing mode of the EVaRT program. First, each trial was inspected for accurate marker labeling. Trials were then cropped to remove data that were collected while subjects are outside of the optimal capture volumes[7]. After all trials were edited a file conversion program was executed to combine the video and FP signals into a C3D file for each trial. The C3D trials were processed and analyzed from this point on using a Visual 3D (C-Motion) software program. The C3D trials from the static standing trial and the digitizing trial were combined to create a static pointer file. The pointer file was then used to define model characteristics based on marker placement, segment definitions, and joint axes. A custom script program or command pipeline was then used to create a subject specific model using the static pointer file. Subject specific height and weight information were used to estimate segment masses and inertial properties (e.g. COM location).

The static pointer file and a model template were then used to create an interactive CMO model file for each subject. Once the CMO file was created the remaining motion (walking) trials were loaded into the CMO file. After all of the over-ground trials were loaded, force platform assignments were visually inspected and inaccurate event labels

[7] For the gravel data the first step onto the gravel surface was excluded from analysis by cropping.

were deleted. The motion (walking) trials were then processed using a 4^{th} order low-pass Butterworth filter with a cut-off frequency of 6 Hz.

Several of the dependent variables for this study were defined using initial contact or heel strike (HS) events that occur with each cycle of stepping. Heel strike (HS) events were calculated automatically for the main walkway using two methods, the first method for the level surface heel-strike events uses the information from good FP data to label HS events based on forces exceeding a 20 Newton threshold. Events labeled by this kinetic method were then used in a pattern recognition algorithm (C-Motion) to label events on the same side during that trial. Although this method was very effective for labeling gait events over level ground, there is no comparable way to label the events over gravel. In the interest of consistency a kinematics only method was used to compute HS data over both surfaces. An algorithm that closely matches the kinetic method involves labeling HS at the contralateral hip extension maxima. To further ensure consistency visual inspection was used to confirm heel strike event timing. Step length was the distance between the heels from the HS of one foot to the subsequent HS on the contralateral foot. Step width was the perpendicular distance between heel of one side at HS and the stride vector of the contralateral side. In straight line walking average step width was equal from side to side. Step time was defined as the time between subsequent HS events. Right step time was defined, as the difference in time between left HS and right HS and left step time was the difference between right HS and left HS.

Table 3-3: Mass proportions
Derived by Dempster (1959).

Foot	0.0145
Shank	0.0465
Thigh	0.100
Hand	0.006
Forearm	0.016
Upper Arm	0.028
Pelvis	0.142
Thorax/Abdom	0.355
Head	0.081
Trunk	0.497

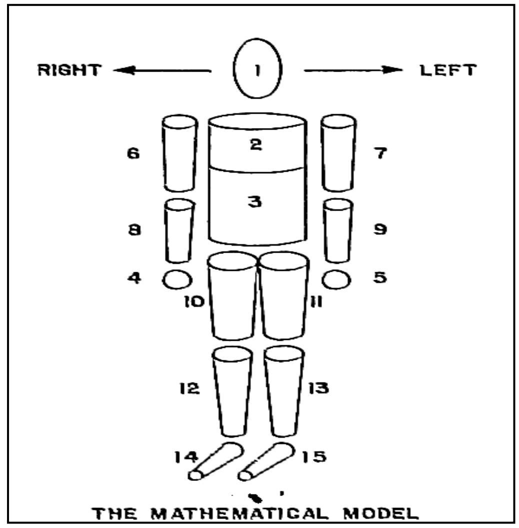

Figure 3-4: Geometric model taken
from Hanavan (1964).

For estimates of DSM, a 15-segment model (feet, shanks, thighs, pelvis, trunk, head, arms, forearms, and hands) was used to estimate whole body center of mass as the weighted average of all of the segments of the body (Robertson 2004). The following equations are used to describe COM estimation for three dimensions with the COM being identified at (X_0, Y_0, Z_0):

$$X_0 = \frac{f_1 M x_1 + f_2 M x_2 + f_3 M x_3 + \cdots + f_n M x_n}{M} = f_1 x_1 + f_2 x_2 + \cdots + f_n x_n \qquad \text{Equation 3-4}$$

$$Y_0 = \frac{f_1 M y_1 + f_2 M y_2 + f_3 M y_3 + \cdots + f_n M y_n}{M} = f_1 y_1 + f_2 y_2 + \cdots + f_n y_n \qquad \text{Equation 3-5}$$

$$Z_0 = \frac{f_1 M z_1 + f_2 M z_2 + f_3 M z_3 + \cdots + f_n M z_n}{M} = f_1 z_1 + f_2 z_2 + \cdots + f_n z_n \qquad \text{Equation 3-6}$$

Where f_n is the percentage of body mass (Table 3-3) represented by each segment, x_n, y_n, z_n, are the coordinates for the COM of the segment, and M is the mass of the body.

The total body mass can actually be removed through division so that all that is needed to determine the whole body COM is the fraction of the mass that is accounted for by each segment and the coordinates for the COMs for each segment (Winter 2005). The DSM minima generally occurred shortly after HS, during weight acceptance on the leading leg side. In other words, each HS has a corresponding DSM minimum.

Frontal plane DSMs were evaluated due to the fact that most falls occur in a lateral direction and falls in the lateral direction are more likely to lead to injury such as hip fractures (Greenspan, Myers et al. 1998; Hof, van Bockel et al. 2007). To calculate frontal plane DSMs the vertical projection of the center of mass location on the ground (CoM), center of mass velocities ($V_{\mathbf{o}}$), leg length, and the location of the base of support (BOS) must be known or estimated (Hof, Gazendam et al. 2005). The equation for DSM is restated below (Equation 1-1):

$$DSM = BOS - CoM - (V_o * (h/g)^{1/2}) \qquad \text{Equation 3-7}$$

Where BOS is a boundary of the base of support, CoM is the vertical projection of the COM on the ground, $V_{\mathbf{o}}$ is the velocity of the COM in the direction of the lateral BOS boundaries, h for the frontal plane is estimated at 1.34 x leg length (m), and g is the gravitational constant (9.81 m/s^2) (Hof, Gazendam et al. 2005). The term $(h/g)^{1/2}$ is equal to the period of a pendulum and is held constant when using the IPM. When multiplied by velocity, $(h/g)^{1/2}$ also normalizes time so that units for this product are in meters or centimeters. For our estimation of BOS margin in the frontal plane (z-coordinate) used the 5th metatarsal marker for each foot[8].

In a static situation the difference between BOS and COM is all that is needed to determine stability margins. In dynamic situations the velocity in the direction of the BOS margin must also be considered. The DSM provides a more conservative estimation of stability when compared to the static equation because the velocity at heel strike is in

[8] The radius of the 5th metatarsal marker is subtracted in the direction of the marker base to provide a closer estimate of the anatomical landmark for BOS calculations.

the direction of the BOS. Velocity of the COM was calculated as the first time derivate of the position data.

Data Analysis

Statistical analyses were performed using SPSS 11 (SPSS Inc, Chicago, IL). Data on age, height, weight, gender, leg length, body-mass index, activity level, and general health histories were collected for all participants. Means and standard deviations are reported for demographic data and for the dependent variable. Dynamic stability margins (DSMs) were calculated for more than 10 steps, per side, for each combination of walking speed and surface. In addition to descriptive statistics, data were analyzed using a 2 x 5 ANOVA with surface and speed as the independent variables. Post hoc analyses were conducted using the estimated marginal means in pair wise comparisons if main effects were significant ($p<0.05$). A Bonferroni adjustment was be used to account for multiple comparisons.

IV. RESULTS

Twenty-two subjects volunteered to participate in this walking study after reading and signing an informed consent document (Appendix B). Two subjects were excluded due to a history of orthopedic injuries that were part of the exclusion criteria, but were not identified during screening. Three sets of data were lacking in quality, probably due to marker slippage. One other subject was slightly older than the inclusion criteria (3 years older), but these data did not differ from the mean, so he is included in the final analysis. Seventeen sets of data are included in this report (4 females and 13 males). Demographic information for all subjects are listed in table 4-1.

Table 4-1: Demographic information for young healthy subjects.

Healthy	Age	Gender	Height (m)	Leg (m)	Mass (kg)	BMI (kg/m^2)
S1	27	F	1.58	0.80	53.6	21.5
S2	19	F	1.60	0.87	59.1	23.1
S3	18	F	1.55	0.77	52.7	21.9
S4	18	F	1.73	0.88	70.9	23.7
S5	19	M	1.80	0.94	61.4	18.9
S6	29	M	1.73	0.89	68.2	22.8
S7	18	M	1.83	0.92	86.4	25.8
S8	23	M	1.83	1.00	83.2	24.8
S9	20	M	1.83	0.96	86.4	25.8
S10	21	M	1.68	0.89	73.6	26.1
S11	30	M	1.79	0.95	82.7	25.8
S12	20	M	1.83	0.97	79.6	23.8
S13	18	M	1.68	0.82	86.4	30.6
S14	18	M	1.73	0.90	71.8	24.0
S15	18	M	1.79	0.95	85.0	26.5
S16	34	M	1.70	0.89	86.4	29.9
S17	38	M	1.90	1.05	88.6	24.6
Mean	22.8		1.70	0.91	75.1	24.7
±SD	6.4		0.10	0.07	12.3	2.9

Our hypothesis that the uneven surface would require a larger DSM was not supported by our study results (p=0.307). Additional statistical testing for main effects revealed a main effect due to walking speed (p<0.001).

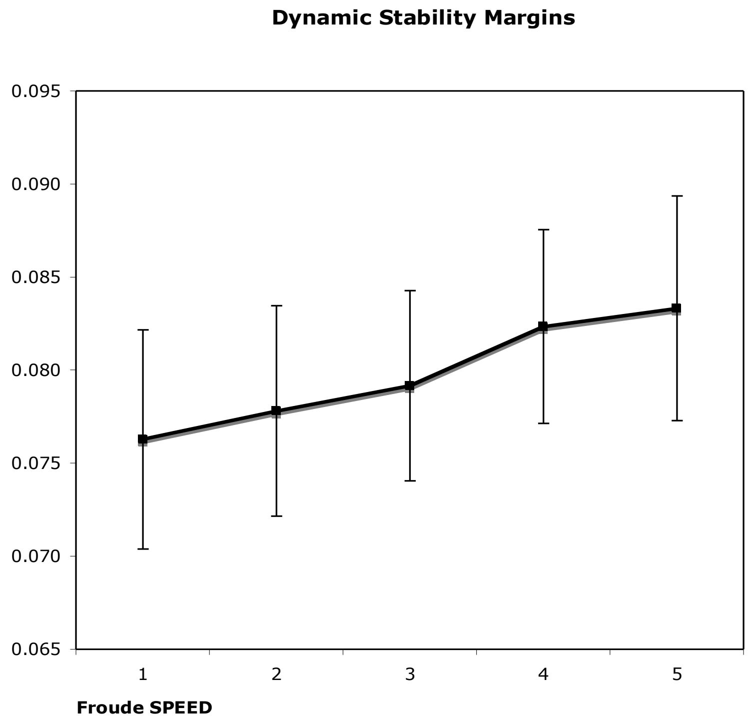

Figure 4-1 Average dynamic stability margins in young healthy adults at five normalized walking speeds (95% CI).

There was a significant linear relationship between DSMs and walking speed (p<.001) (Figure 4-1). There were no significant interactions between surfaces and speeds (p=0.873) (Table 4-2). Post hoc analysis indicated that the predicted dynamically optimal walking speed (Froude 3) was significantly different for DSM than speeds 4 and 5. There were no significant differences between the first three walking speeds, 1-3, or the last two walking speeds, 4-5, (Table 4-3).

Table 4-2: Dynamic stability margins in young healthy adults at five normalized walking speeds. *Greenhouse-Geisser correction for degrees of freedom.

DSM Source	Sum of Squares	df*	Mean Squared	F	Sig.
SPEED	2.284E-03	2.749	8.310E-04	18.439	.000
Error (Speed)	1.858E-03	41.230	4.507E-05		
SURFACE	4.126E-05	1	4.126E-05	1.112	.307
Error (Surface)	5.542E-04	15	3.695E-05		
SPEED * SURFACE	7.830E-06	1.409	5.558E-06	.069	.873
Error (S*S)	1.697E-03	21.131	8.033E-05		

Table 4-3. Pairwise comparisons (Post hoc) of walking speeds on DSMs.
a Adjustment for multiple comparisons: Bonferroni. Based on estimated marginal means.
* The mean difference is significant at the .05 level.

(I) SPEED	(J) SPEED	Mean Difference (I-J)	Std. Error	Sig.[a]	95% CI for Difference	
					Lower Bound	Upper Bound
1	2	-1.524E-03	.001	.785	-4.178E-03	1.129E-03
	3	-2.879E-03	.001	.123	-6.207E-03	4.490E-04
	4	-6.062E-03*	.001	.000	-9.556E-03	-2.568E-03
	5	-7.047E-03*	.001	.001	-1.154E-02	-2.552E-03
2	1	1.524E-03	.001	.785	-1.129E-03	4.178E-03
	3	-1.355E-03	.001	.441	-3.381E-03	6.713E-04
	4	-4.538E-03*	.001	.001	-7.357E-03	-1.719E-03
	5	-5.523E-03*	.001	.001	-8.848E-03	-2.198E-03
3	1	2.879E-03	.001	.123	-4.490E-04	6.207E-03
	2	1.355E-03	.001	.441	-6.713E-04	3.381E-03
	4	-3.183E-03*	.001	.003	-5.425E-03	-9.416E-04
	5	-4.168E-03*	.001	.027	-7.985E-03	-3.521E-04
4	1	6.062E-03*	.001	.000	2.568E-03	9.556E-03
	2	4.538E-03*	.001	.001	1.719E-03	7.357E-03
	3	3.183E-03*	.001	.003	9.416E-04	5.425E-03
	5	-9.851E-04	.001	1.000	-4.342E-03	2.372E-03
5	1	7.047E-03*	.001	.001	2.552E-03	1.154E-02
	2	5.523E-03*	.001	.001	2.198E-03	8.848E-03
	3	4.168E-03*	.001	.027	3.521E-04	7.985E-03
	4	9.851E-04	.001	1.000	-2.372E-03	4.342E-03

V. DISCUSSION

Measurements of dynamic stability margins provide a relative measure of the extrapolated center of mass within the base of support during locomotion. Modern gait laboratories have the capacity to measure elements of DSMs. This capacity has yet to reach a level of recognition that is required for mainstream acceptance and practical application in the biomechanics literature. Utilizing a study design with a broad range of normalized walking speeds over a FLS provided normative values for how DSMs change in response to changes in walking speeds in 17 young healthy adult subjects. Testing the same speeds over a URS provided insights into DSM regulation when surface conditions provide inconsistent proprioceptive feedback. The DSMs in healthy subjects will provide a basis for comparative analysis with patient populations. Contrary to our hypothesis, our findings indicated that the URS was not a significant challenge to dynamic XcoM control in young healthy adults.

This was the initial investigation of the Center for the Intrepid (CFI) URS as a functional test surface. The minimal change in average minimal DSM in healthy young adults as they moved from a FLS to the URS was somewhat unexpected due to the fact that uneven surfaces are often associated with falling (global instability) (Niino, Kozakai et al. 2003). The fact that our young healthy adults were able to adapt to both surfaces and maintain consistent between surface DSMs at multiple speeds may further implicate the DSM as a measure of interest when attempting to discriminate between normal and abnormal dynamic stability. Although this consistency could be due to coincidence, the maintenance of a specific relationship between base of support and XcoM has both a mechanical and intuitive basis (Hof, Gazendam et al. 2005).

Our findings were consistent with other findings in healthy subjects over a different challenging surfaces however (Richardson, Thies et al. 2005; DeMott, Richardson et al. 2007). These previous studies did not find a difference in step variability in unimpaired subjects due to a challenging surface, but did find a difference when subjects with known fall risk were compared to unimpaired subjects. This difference between groups was not discernable over the level surface conditions (Richardson, Thies et al. 2004b; Richardson, Thies et al. 2005; Thies, Richardson et al. 2005a; DeMott, Richardson et al. 2007; Richardson, Thies et al. 2007). A major limitation to these studies is that they did not control for walking speed, which clearly has an effect on variability as well as DSMs. The utility of using our URS to discriminate between fallers and non-fallers is yet to be determined.

Faster walking speeds affected frontal plane DSMs in our study; this was not reported previously (Hof, van Bockel et al. 2007). Hof used three normalized walking speeds that were very similar to our first three speeds, Froude 1-3. We found a similar result at these walking speeds. The fact that Hof's study had only six subjects may indicate that his study design had too few subjects to show a difference when a difference was actually present in a larger sample (type I error). We had 17 subjects and had the same result at approximately the same speeds. Assuming a small sample size was not a limitation to Hof's statistical power, the difference between walking over a firm level surface and walking on a treadmill may also account for less difference in stepping parameters found in Hof's study. Dingwell hypothesized that, motorized treadmill walking may be inherently less variable than over-ground walking (Dingwell, Ulbrecht et al. 1999; Dingwell, Cusumano et al. 2001). In a study of 10 healthy adults Dingwell concluded that, motorized treadmills may produce misleading or erroneous results in situations where changes in neuromuscular control are likely to affect the variability and/or stability of locomotion (Dingwell, Cusumano et al. 2001). Dingwell did not collect data on DSMs in his previous studies, so his conclusions may be limited in this respect. We did not collect data from treadmill trails for comparison to over-ground results in this study. This might be a useful comparison for future consideration when using DSMs as an outcome measure. Overall, our FLS and our URS did not cause a different result than reported for treadmill walking. Fortunately, we expanded on previous research by adding 2 faster walking speeds.

The significant increase in average minimal frontal plane DSMs at faster walking speeds, over both surfaces, indicates that a larger DSM is a normal response to an increase in walking speed. A further analysis of the step width and displacement of the COM in the frontal plane may provide additional insights into this phenomenon. Orendurff demonstrated that as humans walk faster the COM displacement and step width decrease in the frontal plane (Orendurff, Segal et al. 2004). A larger difference between frontal plane XcoM and step width provides us with the explanation for an increase in DSM (BOS-XcoM).

Based on our findings it is reasonable to exclude two of our walking speeds, 1 or 2 plus 4 or 5, and still have the same results. In patient populations, the additional trials required to collect all 5 speeds may exceed the endurance level of participants and could lead to confounding results due to fatigue. A three-speed study design, centered on the predicted optimal (Froude 3 in this case) +/- 20%, appears to provide an adequate test range of speeds.

Ongoing research should focus on developing feasible evaluation and treatment constructs for patients with known or potential balance deficits. Although static stability measurement should not be diminished as a primary screening tool, they are of limited value in discerning future fallers who are stable in a static setting but challenged in a dynamic world (Boulgarides, McGinty et al. 2003). A paradigm shift is needed to advance dynamic stability measurement as a readily available tool in the study of human performance.

Based on this discussion, future research question should be directed at: 1) comparing the results of our young healthy adults to patients with known fall histories or balance deficits, 2) determine if there is a difference in DSM response to walking speeds over a level surface compared to a treadmill, and 3) determine which components of the DSM change in order to get the observed differences.

VI. RESEARCH METHODS

Study 2: The Effects of Walking Speed and an Uneven Rocky Surface on Dynamic Stability Margins in Young Adults with Unilateral Trans-Tibial Amputations

Introduction

Falls are common in patients with lower limb amputations (LLA) and uneven surfaces pose greater threats to dynamic stability than level surfaces (DeMott, Richardson et al. 2007). A high ceiling effect associated with fall risk assessments in young patients with LLA makes it difficult to identify those who might need additional interventions (Gauthier-Gagnon and Grise 2006). Although this study did not attempt to identify fall risk, it attempted to characterize a quantitative method, DSMs, in a population with known unilateral physical impairments. The effect of unilateral trans-tibial amputation (TTA) on DSMs was added to the previously stated independent variables of speed and surface in a factorial design. In this study residual limb lengths and time in prosthesis were deemed to be potential covariates (Isakov, Burger et al. 1996; MacKenzie, Bosse et al. 2004; Hofstad, van der Linde et al. 2006). Longer residual limb length generally provides a better functional outcome for trans-tibial amputees (Isakov, Burger et al. 1996). Longer time in prosthesis was identified as a significant contributor to function in a study conducted by Hofstad et al. (Hofstad, van der Linde et al. 2006).

RESEARCH AIMS/HYPOTHESES

Aim: To determine the effects of surface and walking speed on frontal plane dynamic stability margins in young adults with trans-tibial, while accounting for residual limb length and time in prosthesis.

Hypothesis 1: Average minimal DSMs will be greater when walking over the uneven rocky surface (URS) at any given speed in young adults with TTA (main effect for surface).

We anticipated a significant main effect for surface, namely that the uneven rocky surface would require a more conservative gait pattern (i.e. larger DSM).

Hypothesis 2: Average DSMs will be greater on the involved side when compared to the uninvolved side (main effect for side).

Hof found increased average DSMs on the involved side of patients with trans-femoral amputations (TFA). We anticipated a similar response in subjects with TTA, i.e., a significant main effect for side. If we did not find an asymmetry due to amputation, the assumption that asymmetry is an acceptable trade-off for improved stability in subjects with unilateral TFA does not apply to patients with unilateral TTA.

Hypothesis 3: Average DSMs will increase as walking speed increases in young adults with TTA (main effect for speed).

Hof found increased average DSMs on the involved side of patients with trans-femoral amputations (TFA), but not due to speed. We included a much faster walking speed in our study and expected a significant main effect at faster speeds in our subjects with TTA due to the increased velocity.

RECRUITMENT AND SCREENING OF SUBJECTS

Twenty-two active duty Service members, 18-35 years old, with traumatic lower limb amputations were recruited from the Medical Holding Company at Brooke Army Medical Center (BAMC), Ft. Sam Houston, Texas. Recruitment was done through clinical contact with subjects as part of their routine rehabilitation. If a potential subject expressed a verbal willingness to participate in this study s/he was briefed regarding time requirements, instrumentation, and the walking protocol. An appointment was made for data collection and at that time an informed consent was obtained in writing by the principle investigator, an associate investigator, or a research assistant listed in the proposal document.

Potential subjects filled out a health history questionnaire and underwent a brief physical exam to verify that inclusion and exclusion criteria were met. Inclusion criteria were: lower limb amputation(s) and were able to complete all activities listed on the Locomotor Capabilities Index-5 (LCI-5) without external assistive device (Appendix D). Exclusion criteria for this study were: Traumatic brain injury (Glasgow Coma Scale (GCS) < 13), loss of vision, vestibular dysfunction, pain $\geq$ 4/10, unhealed wound, active infection, unable to stand > 60 minutes with breaks. Based on clinical testing, our inclusion criteria limited participation to patients with unilateral LLA and high functioning bilateral trans-tibial amputees.

Exclusion criteria for this study included: a history of debilitating LBP prior to amputation or as a result of trauma that led to amputation, a history of surgery to the spine, confirmed nerve root compression with radiculopathy, other residual limb problems, the presence of concomitant injury, or pending litigation.

All subjects were free of orthopedic and neurological disorders to the intact side that might have affected their ability to complete the testing protocol. A brief physical exam included joint range of motion, balance and strength testing. Complications that may have lead to skin breakdown, discomfort, or injury were an immediate basis for stopping a trial, delaying or discontinuing subject participation.

This study did not require invasive procedures. Objectives were within current practices for evaluation and treatment of patients with LLA. Subjects were required to demonstrate a fast walking pace and enough cardiovascular endurance to walk for at least ½ mile, with rest as needed.

STUDY DESIGN AND SAMPLE SIZE

A single session repeated measures quasi-experimental design was conducted. Subjects were asked to walk over two surface conditions including a level over-ground surface and an uneven gravel surface. Self-selected walking speeds are routinely collected as part of clinical trials and were collected at the beginning as part of the laboratory orientation. Four dimensionless Froude (control) speeds were also assigned in pseudo-random order. Sample size estimation was based on standard deviations reported by Hof (2007), a 2-factor analysis of variance (ANOVA) design, α=0.05, a moderate effect size (0.25), and a desired power of 0.80. From this analysis, a minimum of 12 subjects was recommended. We expected approximately 97% males based on reported injury statistics for traumatic amputation in the military. Subjects were recruited based on recommendations from their physical therapists. This involved chance matching of level of amputation with rehabilitation status. The subjects who were most likely to meet the inclusion criteria had isolated unilateral trans-tibial amputations. Patients with other types of LLA were included if inclusion/exclusion criteria were met.

EXPERIMENTAL PROTOCOL

The experimental protocol for this study was very similar to the design already described for young healthy subjects. The differences between the studies are explained here. Walking speed order was randomized in the same way as described for the healthy subjects with one exception: healthy subjects were asked to walk at the fastest standardized speed (Froude 5) during each set of walking trials, while subjects with amputations were only asked to perform trials at this fastest speed at the end of the walking protocol. This was done to prevent fatigue in this population that could possibly lead to inconsistent results or early withdrawal from the study. Froude 5 was the fastest speed and we anticipated that some subjects in this study of patients might not be able to complete this speed either over ground, over gravel, or over both surfaces. It was determined that five good trials at all speed and surface combinations was preferable to risking subjects dropping out prior to completing all conditions due to fatigue.

DATA COLLECTION

Data on age, height, weight, gender, leg length, residual limb length, body-mass index, activity level, preferred walking speed, time in prosthesis, and general health histories were collected for all participants. The same processes and equipment were used for data collection as in the previously described study.

DATA PROCESSING

The same process was followed in this study to process data as was previously described for healthy subjects. Prostheses were modeled in the same way as able body segments. Segment properties were modeled as previously described[9].

DATA ANALYSIS

Statistical analyses were performed using SPSS 11 (SPSS Inc, Chicago). Inferential statistics were used for hypothesis testing based on the following plan: 1) A 2 x 2 x 3 ANCOVA with side, surface and speed as the independent variables, time in prosthesis and residual limb length as covariates, and 2) Post hoc analyses were conducted using the estimated marginal means in pair wise comparisons if main effects were significant ($p<0.05$). A Bonferroni adjustment was be used to account for multiple comparisons.

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[9] Prosthesis limb mass is typically 40% less than the unaffected limb. The overall affect on whole body COM is likely minimal when considering the contribution of the residual limb to the segment and the substantial contribution of the head arms and trunk to the COM location.

VII. RESULTS

Four subjects had unilateral trans-femoral amputations, two subjects had bilateral trans-tibial amputations (TTA), one subject had a knee disarticulation, and one subject with TTA had ataxia that was not obvious during screening but became evident during testing. Twelve sets of data for subjects with traumatic unilateral TTA are included in this report (1 female and 11 males). Demographic information for these subjects is listed in table 7-1.

Table 7-1: Demographic information for subjects with unilateral trans-tibial amputations.

TTA	Age	Gender	Height (m)	Leg (m)	Mass (Kg)	BMI	Residual Limb (cm)	Weeks in Prosthesis
S1	26	M	1.80	0.93	67.5	20.8	15.5	12
S2	32	M	1.86	0.86	83.9	24.2	18.5	26
S3	29	M	1.75	0.94	75.5	24.7	18.8	8
S4	32	M	1.76	0.92	77.3	25.0	10.3	21
S5	20	M	1.93	0.91	119.8	32.2	24.8	8
S6	27	M	1.77	0.95	85.9	27.4	13.5	4
S7	23	M	1.80	0.90	94.1	29.0	24.7	8
S8	27	M	1.88	0.94	96.6	27.3	13.5	12
S9	24	M	1.81	0.95	90.9	27.8	21	4
S10	32	F	1.65	0.91	76.8	30.9	14.5	16
S11	30	M	1.97	0.84	105.5	27.2	25	36
S12	35	M	1.71	1.05	93.0	31.8	20	52
Mean	27.2		1.80	0.93	88.9	27.4	18.3	17.3
± SD	4.7		0.10	0.05	14.4	3.4	5.0	18.3

The ANCOVA results are displayed in table 7-2. In this analysis there was a within subjects main effect due to surface ($p=.011$, figure 7-1), no main effect due to speed ($p=.656$), and no main effect due to side ($p=.211$), involved vs. uninvolved. There were no significant within subjects interactions between our independent variables, but there was a trend for a side x speed interaction ($p=.058$). There was a significant between subjects effect for residual limb length (p=.029). Longer residual limb lengths were significantly correlated to larger DSMs in 4 out of 6 walking conditions (table 7-3).

Table 7-2: ANCOVA summary table for within subjects results for DSMs in young adults with unilateral trans-tibial amputations. *Greenhouse-Geisser correction for degrees of freedom. Limb length and time in prosthesis included in model as covariates.

DSM Source	**Sum of Squares**	**df***	**Mean Squared**	**F**	**Sig.**
SIDE	7.653E-04	1.000	7.653E-04	1.815	.211
Error (Side)	3.794E-03	9.000	4.216E-04		
SPEED	4.388E-05	1.956	2.243E-05	.426	.656
Error (Speed)	1.858E-03	17.605	5.271E-05		
SURFACE	1.233E-03	1.000	1.233E-03	10.205	.011
Error (Surface)	1.087E-03	9.000	1.208E-04		
SIDE * SPEED	1.921E-04	1.685	1.140E-04	3.631	.058
Error (SD*SP)	4.762E-04	15.167	3.140E-05		
SIDE * SURFACE	7.830E-06	1.409	5.558E-06	.069	.873
Error (SD*SU)	8.204E-04	9.000	9.116E-05		
SPEED * SURFACE	1.732E-04	1.696	1.021E-04	2.513	.120
Error (SP * SU)	6.201E-04	15.266	4.062E-05		
SIDE * SPEED* SURFACE	1.030E-04	1.776	5.801E-05	1.308	.294
Error (SD *SP * SU)	7.086E-04	15.983	4.433E-05		

The consistent positive correlations between residual limb lengths and DSMs indicate that longer residual limbs are somewhat predictive of larger DSM. This relationship was strongest at the fastest walking speed over the FLS (r^2=. 62) and weakest at the fastest walking speed over the URS (r^2=. 11). There was no main effect for time in prosthesis (p=.741).

Table 7- 3 Pearson Correlations OG = Overground; RO = Rocks; 1-3 = Froude Speeds

	Residual Limb	OG 1 DSM	OG 2 DSM	OG 3 DSM	RO 1 DSM	RO 2 DSM	RO 3 DSM
Residual Limb (r-values)	1	.649*	.678**	.788**	.694**	.357	.336
OG 1 DSM		1	.927	.854	.719	.335	.484
OG 2 DSM			1	.932	.751	.497	.641
OG 3 DSM				1	.846	.563	.673
RO 1 DSM					1	.629	.619
RO 2 DSM						1	.813
RO 3 DSM							1

* Correlation (r-value) is significant at the 0.05 level (1-tailed).
** Correlation (r-value) is significant at the 0.01 level (1-tailed).

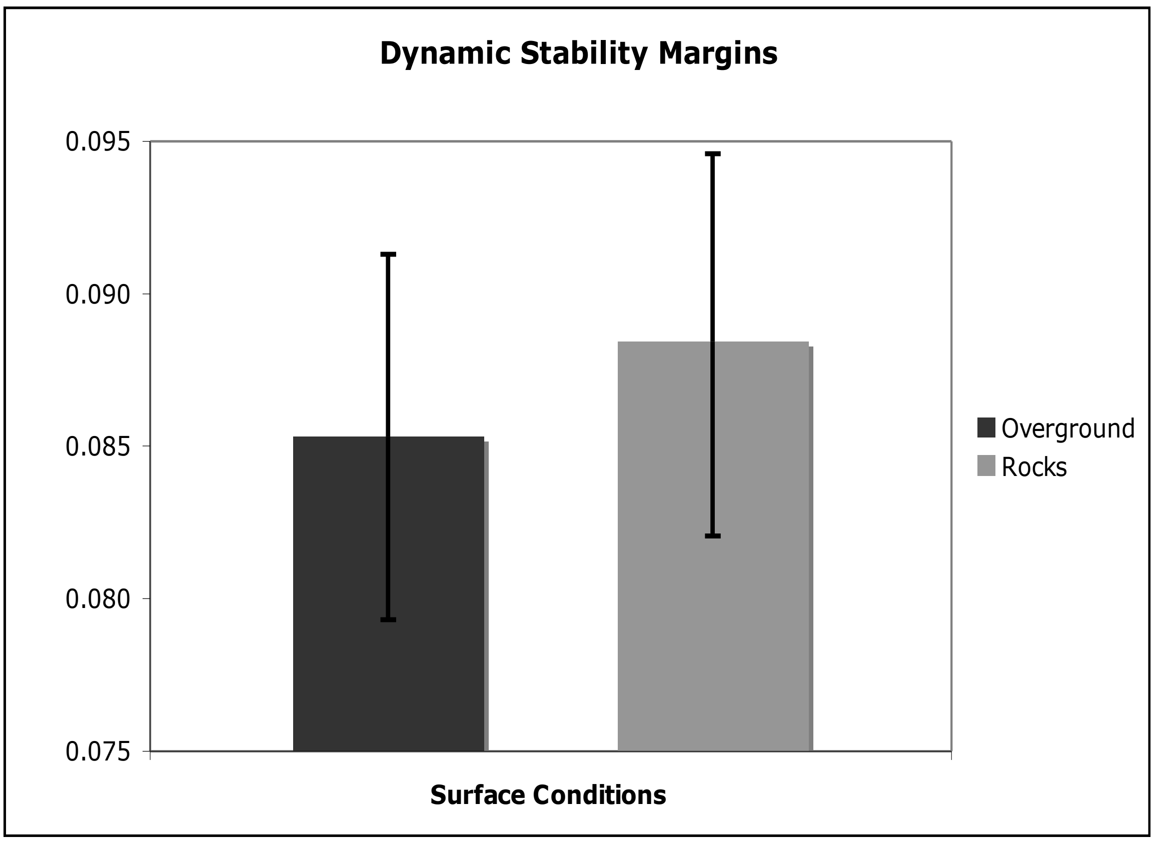

Figure 7-1. Average dynamic stability margins in subjects with TTA over two surface conditions (95% CI). Evaluated at covariates appeared in the model: Residual limb = 18.3 cm, Time in prosthesis = 17.25 wks.

VIII. DISCUSSION

During rehabilitation, the degree of success is ultimately determined by the timely facilitation of rehabilitation goals. One of the most important goals for a patient with a LLA is the safe resumption of walking. Independent ambulation is recognized as a milestone that must be achieved in order to gain self-sufficiency (Narang, Mathur et al. 1984). In young active patients with LLA, the addition of challenging surface conditions during gait training is crucial for establishing functional competence. The increasing emphasis in rehabilitation on providing evidence-based assessments and treatment programs calls for the addition of valid quantitative measures of dynamic stability (Gajewski and Granville 2006; Murphy, Tinetti et al. 2007; Tyson, Watson et al. 2007).

Dynamic stability margin appears to provide a quantitative measure of COM control during whole body movements that is easy to comprehend and provides the assurance of construct validity. Researchers and clinicians who understand the inverted pendulum model of COM control within the base of support do not require much imagination to grasp the extrapolation that Hof provides for dynamic situations (Hof, Gazendam et al. 2005).

Our first hypothesis, main effect due to surface, was supported when we factored time in prosthesis and residual limb length as covariates. Isakov found that subjects with unilateral TTA and residual limb lengths shorter than 15.1 cm had more thigh atrophy and less strength than those with limb lengths longer than 15.1 cm. He suggested that the shorter lever arm had the disadvantage of creating less control over the leg by the thigh muscles (Isakov, Burger et al. 1996). Although four of our subjects had residual limb length of less than 15.1 cm, the average residual limb length was 18.3 cm. Adjusting for the difference in residual limb length in our subjects revealed a within subjects main effect due to surface. This finding indicates that the larger DSM due to the URS is an adaptation due to TTA because it was not present in our earlier study of young healthy adults.

The ability to discriminate between a patient population and young healthy subjects by using DSMs provides a theoretical argument for using DSMs. The strong relationship between residual limb length and DSM may also be useful for developing prediction algorithms for DSMs based on residual limb length.

Interestingly our second and third hypotheses were not supported by our ANCOVA results. Limb side (involved vs. uninvolved) did not differ significantly due to surface conditions. Hof found increased average DSMs on the involved side of patients with trans-femoral amputations (TFA). We did not find a similar result in our subjects with unilateral TTA. In fact, the involved side tended to have a smaller DSM than the uninvolved side. Hof's claim, that a larger DSM or asymmetry is a reasonable adaptation in subjects with TFA, does not appear to apply to our subjects with TTA. This result is probably due to some combination of the following factors: 1) the presence of a knee joint and residual limb in our subjects; the need for the patient with TFA to actively circumduct, swing leg out to side, in order to clear the foot during swing phase of gait. This may naturally lead to a wider step width when compared to subjects who can actively flex their knees to clear the foot. 2) the difference in age between our subjects and Hof's (Hof's were much older), and 3) the more recent rehabilitation expose with emphasis on gait symmetry at the CFI. Hof's patients had much more time in prosthesis, which means longer time since rehabilitation.

Our third hypothesis was not supported when residual limb lengths and time in prosthesis were factored into the analysis. Speed did not have a significant within subjects main effect on DSMs in this study. The difference of +/- 40% from the middle speed (Froude 3) should have been more than enough to show a difference if one truly existed[10]. The nearly significant trend of a speed by side interaction may have reached significance with more subjects in the study and indicates that this is likely an important consideration.

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[10] There was a between subjects difference in DSM due to speed, but our interest was in within subjects effects.

Future studies should consider the length of the residual limb as an important and relevant covariate. Had we ignored this factor, we would have missed the difference that existed between our patient population and our young healthy adults. Isakov indicated that a shorter residual limb results in functional deficits that are related to decreased thigh girth and strength, poorer socket fit and stability of the prosthesis, decreased proprioception, and a decreased lever arm (Isakov, Burger et al. 1996). The role that residual limb length plays in balance may be deduced from a meta-analysis that was conducted by van Velzen in conjunction to Isakov's conclusions. Forty-eight articles were reviewed to determine predictors of physical capacity and walking ability after lower limb amputation. Strong evidence was found for the relationship between balance and walking ability. Likewise there was strong evidence for deterioration of muscle strength and balance due to amputation (van Velzen, van Bennekom et al. 2006).

The assumptions that longer residual limb length is related to improved thigh strength and that muscle strength is related to balance, points to the interpretation that longer residual limb length is related to better balance. Applying this logic to our results suggests that the larger DSMs associated with a longer residual limb may also represents better balance (i.e. dynamic stability). We did not measure strength directly as part of this study design, so this assumption may be the basis for a later hypothesis rather than a statement of fact. The finding that larger DSMs were less related to limb length over our URS at faster walking speeds may be due to the destabilizing effect of the terrain pit and the inconsistent nature of pushing off and landing on a gravel surface with an artificial foot and ankle. From this, it appears that the URS is effective at decreasing the advantage of a longer residual limb, as walking speeds approach over-ground self-selected and faster pacec. Regardless of the relationship between residual limb length and DSMs there was a strong tendency toward symmetry in side-to-side DSM measurements. This was in contrast to Hof's finding in six subjects with TFA (Hof, van Bockel et al. 2007). Therefore the statement that asymmetry is an acceptable trade-off for stability, is not necessarily true for patients with TTA. This contention can be argued especially in subjects with TTA and longer residual limbs who have presumably greater strength and limb control. In subjects with shorter residual limbs, additional efforts to strengthen proximal thigh and hip muscles through rehabilitation and strength training programs may be worthwhile. Establishing baseline measures of DSM and strength may prove to be a useful way to cross-validate the efficacy of strength training programs and the utility of DSMs as an indicator of functional improvement in this population.

The time in prosthesis was not a significant covariate in this investigation. Five of our subjects had eight weeks or less in prosthesis. Four weeks in prosthesis was the shortest amount of time deemed necessary to prepare a subject, prosthesis (fine-tuning), and residual limb for the activities in this study.

An important goal of this research was to assess dynamic stability margins using realistic and challenging over-ground walking trials in a young adult population with traumatic TTAs. In spite of attempts to make conditions realistic, it is recognized that controlled clinical settings are not exactly matched to real-world environments and conclusions may not be generalized to all surface conditions or environmental constraints. Regardless of environmental conditions, the ability to quantify dynamic stability margins as an outcome measure has the potential to be of great value in evaluating treatment programs, fine-tuning prosthetic adjustments, and developing and validating fall risk assessment tools for dynamic conditions. Techniques used in this study may also prove useful in evaluating current clinical balance assessment tools using a dynamic rather than a static reference. Developing methods that require less set up time and provide the same degree of precision will ultimately make DSMs more attractive to the clinician. The potential to estimate COM position and velocity by using a cluster of markers or even a single marker in relation to foot markers would greatly reduce time requirements and likely have negligible effects on results.

APPENDICES

APPENDIX A

HEALTH HISTORY QUESTIONNAIRE

"The Effects of Walking Speed and an Uneven Surface on Dynamic Stability: A Lower Extremity Amputee Study"

IRB #: **Subject ID:** ____________________

OPTIONAL: Please indicate whether or not you wish to be contacted after this study; please circle a selection and then initial. Yes / No ________

REQUIRED: This section to be completed by PI or AI

Height:____________ ft./in. = ___________ in. × 0.0254 = ____________ m

Weight: ___________ lbs. × 0.4567 = ___________ kg

BMI (kg/m^2): ____________

Leg length GT to LM R: __________m L: __________m Shoe length:________m

Time in current prosthesis: ____________________ weeks

Type of prosthesis: _________________________________ Settings: ________________

REQUIRED: This section to be completed by participants

1. Are you taking any medications on a regular basis?
   Y / N
   If yes, list drug(s) and reason(s) for taking.

2. Are you currently taking any over-the-counter meds?
   Y / N
   If yes, explain.

3. Do you have frequent headaches?
   Y / N
   If yes, explain (how often, how severe).

4. Do you have any history of back problems, such as low back pain?
   Y / N
   If yes, explain.

5. Do you experience "phantom limb" sensation or pain?
   Y / N
   If yes, explain.

6. Have you ever lost consciousness as a result of trauma?
   Y / N
   If yes, explain (how, how long unconscious, and when).

7. Do you experience episodes of dizziness?
   Y / N
   If yes, explain.

8. Do you have any problems with standing balance?
   Y / N
   If yes, explain.

9. Do you have any drug and/or alcohol dependence?
   Y / N
   If yes, explain.

10. Do you have any significant visual impairments?
    Y / N
    Examples: loss of binocular vision or the presence of double vision
    If yes, explain.

11. Do you have any heart problems or coronary artery disease?
    Y / N
    If yes, explain.

12. Do you have hypertension?
    Y / N
    If yes, explain.

13. Do you have any lung or respiratory problems?
    Y / N
    If yes, explain.

14. Do you use tobacco?
    Y / N
    Pattern?

15. Do you use alcohol?
    Y / N
    Pattern?

16. Do you consume products that contain caffeine (cola, coffee, etc.)?
    Y / N
    Pattern?

17. Do you have any allergies that require medication?
    Y / N
    If yes, explain.

18. Have you experienced a fall while standing or waking in the last 3 months?
    Y / N
    If yes, explain (when and how).

19. (Females only) Are you pregnant?
    Y / N

Self-reported activity level:

How many times a week do you exercise?: ___________________________

How long do you spend exercising on those days?: ___________________________

What intensity level would you say you exercise at?: ___________________________

(e.g. "low", "moderate", or "hard")

APPENDIX B

BROOKE ARMY MEDICAL CENTER
INFORMED CONSENT DOCUMENT
(ICD Template Version 4, Jul 02)

THE EFFECTS OF WALKING SPEED AND AN UNEVEN SURFACE ON DYNAMIC STABILITY: A LOWER LIMB AMPUTEE STUDY

PRINCIPLE INVESTIGATOR: MAJ Shawn J. Scott, SP
Phone: (210) 916-1478 e-mail: shawn.scott1@us.army.mil

If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

DESCRIPTION/PURPOSE OF RESEARCH:

The purpose of this study is to evaluate the effects of walking speed and a gravel surface on the balance in of young adults with traumatic lower limb amputations. A similar number of subjects without amputations will also be evaluated as part of this area of study. The study of balance during walking is related to fall risk and will provide a foundation for future clinical applications and research. Patients with lower limb amputations have a heightened challenge to maintain balance on uneven terrains while walking. How you respond to walking on a gravel surface plus the additional challenge of changing speeds will be measured and analyzed. The results will help to guide future studies and provide a basis for comparison.

This study will enroll approximately 22 subjects over a period of 24 months. During your participation in this study, you will be asked to make approximately 1 outpatient visit to the Military Performance Laboratory at the Center for the Intrepid. Total estimated time to participate in this study is **less than 3 hours.**

You have been selected to participate in this study because you are between the ages of 18 and 35, have a lower limb amputation and have demonstrated independence in walking and normal activities of daily living.

PROCEDURES:

As a participant, you will undergo the following procedures:

- *READ AND SIGN THIS INFORMED CONSENT FORM (10 MINUTES)*
- *LOCOMOTOR CAPABILITIES INDEX-5 QUESTIONNAIRE (5 MINUTES)*
- Health history questionnaire (10 minutes)

- *RANGE OF MOTION AND STRENGTH ASSESSMENT (5 MINUTES)*
- *WALKING PROTOCOL (90 MINUTES)*

Walking protocol: You will be instructed in a specific walking protocol that has been randomly selected to vary order of speeds, up to five speeds. Each speed will be conducted over level terrain and a gravel surface 10 times each for up to 100 walking trials. <u>The estimated total distance walked will be ½ mile</u>. If you feel that this exceeds your capacity please let us know. Rest will be allowed and offered during the study. During this testing, reflective markers will be attached to your body (i.e., arms, hips, legs, feet, trunk, hands, and head). 16 or more digital infrared cameras will see the reflection of the surface markers as you walk on an 18-meter runway or through a gravel terrain pit. The cameras recording your motion will feed the information into a computer that will calculate the positions of the reflective markers. The information recorded during the over-ground gait evaluation will provide us with joint angles as you move and information about how the forces of gravity are distributed across your joints when you walk. The testing session will also be recorded by two normal digital video cameras. Video data will be stored in a locked file cabinet and will only be used if there is difficulty interpreting data collected using the digital infrared cameras.

Your total time commitment for participating in the study will be one session that lasts approximately three hours.

<u>RISKS OR DISCOMFORTS:</u>

Potential risks from participating in the study are minimal. You may experience mild discomfort during the removal of the double-sided tape used to apply the markers. You may also experience fatigue during the testing session and you are encouraged to inform a member of the research team if you need to take a break. If you become fatigued you will be allowed to rest until you are comfortable or decide to discontinue.

This study involves walking over uneven terrain and may result in loss of balance or falls. Stand-by assistance will be provided as needed during trials that involve the uneven surface. Discomfort to the residual limb(s) is possible and should be reported immediately.

This study may involve risks that are currently unforeseeable. If you wish to discuss the information above or any other risks you may experience, you may ask questions now or call the Principal Investigator listed in the Contacts section of this document.

<u>FEMALES ONLY:</u>

If you become pregnant or feel you might be pregnant, contact the Principle Investigator, Major Scott. Please <u>notify him now</u>.

BENEFITS:

There is no direct benefit for participation in this study.

PAYMENT (COMPENSATION):

You will not receive any compensation (payment) for participating in this study.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY:

Choosing not to participate in this study is your alternative to volunteering for the study.

CONFIDENTIALITY AND PRIVACY PROTECTION:

Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the Military Amputee Research Program, other U.S. government agencies, the BAMC Institutional Review Board, and by authorized persons from The University of Texas at Austin.

The records of this study will be stored securely and kept confidential. Authorized persons from The University of Texas at Austin, members of the Institutional Review Board, and have the legal right to review your research records and will protect the confidentiality of those records to the extent permitted by law. All publications will exclude any information that will make it possible to identify you as a subject. Throughout the study, the researchers will notify you of new information that may become available and that might affect your decision to remain in the study.

With the exception of the informed consent sheet and the HIPPA consent sheet, subject names will not be used on any documentation. On receiving informed consent each subject will be given a number code and will be tracked by that code on all other documentation. Paper documents will be kept in a locked file cabinet, inside a laboratory that will have key only access during non-duty hours and on weekends. Non-paper documents and data will be secured on a password protected computerized system.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

ENTITLEMENT TO CARE:

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (Taylor, Dodd et al.) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the

Brooke Army Medical Center Protocol Coordinators, (210) 916-2598 or BAMC Judge Advocate General, (210) 916-2031.

PHOTOGRAPHS:

Permission to take clinical photographs or digital video of you during your participation in this study is requested, and these photographs along with any of the digital video images we record may be then used in presenting this data in both written form (for journal manuscripts) or visual form (in poster presentations, lectures, or other public educational forums). You may decline to be photographed but still participate in the study. Please mark the appropriate box below in reference to this topic:

↑ By checking this box, I _____ (initials) allow photographs to be taken of me during this study and allow these photographs to be used in future educational displays related to this study.

BLOOD & TISSUE SAMPLES:

No blood or tissue samples will be taken as part of this study.

VOLUNTARY PARTICIPATION:

The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. The Principal Investigator or one of his associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify the principle investigator directly or through your health care provider, most likely your physical therapist. Your condition will continue to be treated.
The investigator of this study may terminate your participation in this study at any time if he feels this to be in your best interest.

CONTACTS INFORMATION:

If you have any questions about the study please ask now. If you have questions later, want additional information, or wish to withdraw your participation call the researchers conducting the study

Principal Investigator (PI)
The Principal Investigator or a member of the Military Performance Laboratory staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: MAJ Shawn Scott, SP
Phone: (210) 916-1478

Associate Investigator: Jason M. Wilken, PT, PhD
Phone: (210) 916-1478

You may also contact Lisa Leiden, Ph.D. at The University of Texas at Austin Institutional Review Board for the Protection of Human Subjects, (512) 471-8871
Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent. Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

A signed and dated copy of this form will be given to you.

STATEMENT OF CONSENT:

I have read the above information and have sufficient information to make a decision about participating in this study. I consent to participate in the study.

____________________________ __________________ _____________

Volueer's Signature

Volunteer's Signature **Volunteer's SSN** **Phone #**
Date

Volunteer's Printed Name **FMP** **Sponsor's SSN** **Date of Birth**

Volunteer's Address (street, city, state & zip code)

Advising Investigator's Signature **Date** **Phone Number**
(can only be signed by an investigator whose name is listed in the protocol)

Advising Investigator's Printed Name

Witness' Signature **Date**
(Must witness ALL signatures)

Witness' Printed Name

APPENDIX C

Subject ID________________ Data Session_______________
Dynamic Stability Data Collection in Soldiers with Lower Limb Amputations

Activities checklist:

- ☐ Informed consent
    - o give copy to each subject at end (10 min)
- ☐ Gait Lab Assessment form (age, gender, meds, time in current prosthesis, etc.) (10-15 min)
- ☐ LCI-5 (5 min)
- ☐ Range of Motion Assessment- gross upper extremity, specific lower extremity, NVI, and quick balance screen (5 min)
- ☐ **Leg length** and shoe measurements, height and weight. (5 min)
    - o **Calculate Speeds**
    - o Select walking order (assignment *a priori*)
- ☐ Instrumentation (markers and digitizing) 15 min
- ☐ Safety briefing (demonstration) 5 min
- ☐ Orientation (walk/record self-selected speeds over both surfaces 3-5 times) 5 min
- ☐ Data Collection with practice at prescribed speed prior to each set of trial speeds, raking for every 1-3 trials, and breaks as needed (30 min)
- ☐ Data Collection with practice at selected speed prior to each set of trial speeds, raking for every 1-3 trials, and breaks as needed (30 min)
- ☐ Self-selected speeds over both surfaces 3-5 times
- ☐ Confirm “good” data (5 min)

☐ Health history questionnaire. **<u>Give copy of informed consent.</u>**

☐ After action

Subject ID________________ Data Session_______________

Dynamic Stability Data Collection in Soldiers with Lower Limb Amputations

<u>Forms included:</u>

- Informed consent
- Activities checklist
- Military Performance Laboratory Gait and Motion Analysis Evaluation Data Sheet (Modified)
- Locomotor Capabilities Index-5 (LCI-5)
- Health History Questionnaire (HHQ)
- Walking Speed Chart
- Walking Speed Sequence

APPENDIX D

Locomotor capabilities index-5 (LCI-5); **sub-scale of Prosthetic Profile of Amputee**

Table 1: The LCI With Items Graded on a 5-Level Ordinal Scale (LCI-5)

The common question is "Whether or not you wear your prosthesis at the present time, would you say that you are able to do the following activities with your prosthesis on?"	No (0)	Yes, If Someone Helps Me (1)	Yes, If Someone Is Near Me (2)	Yes, Alone, With Ambulation Aids (3)	Yes, Alone, Without Ambulation Aids (4)
1. Get up from a chair	☐	☐	☐	☐	☐
2. Pick up an object from the floor when you are standing up with your prosthesis	☐	☐	☐	☐	☐
3. Get up from the floor (eg, if you fell)	☐	☐	☐	☐	☐
4. Walk in the house	☐	☐	☐	☐	☐
5. Walk outside on even ground	☐	☐	☐	☐	☐
6. Walk outside on uneven ground (eg, grass, gravel, slope)	☐	☐	☐	☐	☐
7. Walk outside in inclement weather (eg, snow, rain, ice)	☐	☐	☐	☐	☐
8. Go up the stairs with a hand-rail	☐	☐	☐	☐	☐
9. Go down the stairs with a hand-rail	☐	☐	☐	☐	☐
10. Step up a sidewalk curb	☐	☐	☐	☐	☐
11. Step down a sidewalk curb	☐	☐	☐	☐	☐
12. Go up a few steps (stairs) without a hand-rail	☐	☐	☐	☐	☐
13. Go down a few steps (stairs) without a hand-rail	☐	☐	☐	☐	☐
14. Walk while carrying an object	☐	☐	☐	☐	☐

NOTE. In the standard LCI,[4,9] items are scored according to a 4-level ordinal scale: the LCI-5 levels 3 and 4 are merged in a unique level (3, yes, alone).

Taken from Franchignoni, *Arch Phys Med Rehab*, 85: 743-8

GLOSSARY

Preferred Walking Speed (PWS)

Conceptual: The self-selected walking speed. The PWS is often used as a dependent variable in walking studies. Independent variables such as pathology or surface conditions are then selected to determine effects on PWS.

Operational: A person of average height typically has a PWS of approximately 1.2-1.6 m/s. We will report PWS in m/s or as a dimensionless Froude number based on leg length from the greater trochanter to the ground.

Froude number (FN)

Conceptual: A non-dimensional value for normalizing gait speed based on leg length and acceleration due to gravity. The FN is a scalar quantity between 0-1 for walking speed. A FN of approximately .40 is comparable to preferred walking speeds. Although it is possible to run at a FN ≤ 1, a FN > 1 is defined as running (flight phase) from a dynamical perspective.

Operational: Froude number (FN) equation is:

$$FN = V/(g \bullet l)^{1/2}$$

Where V is velocity, g is gravity (9.81 m/s^2), and l is the length from the greater trochanter to the ground in meters.

Static Stability in Human Standing

Conceptual: The functional neuromuscular response to COM movement is the center of pressure position (COP). The COP must be located peripherally to the COM for maintenance of static stability. Even in quiet standing, the center of mass (COM) is constantly moving within the base of support (BOS). In order to maintain standing equilibrium, the center of pressure must oscillate with a greater amplitude than the COM. The ability to resist a step, stumble or fall in standing when leaning or when an external perturbation is applied is used to test the limits of stability. Static stability measures are typically based on normative values by age group.

Operational: The distance from the COM vertical projection on the ground toward the edge of the BOS (either fore-aft or lateral). This can be reported in meters, but centimeters are often reported. This measure does not include the velocity of the COM, which is generally negligible in a static standing situation.

Dynamic Stability in Human Movements

Conceptual: Dynamic stability reflects the ability to resist a trip, stumble or fall during whole body movements, such as walking.

Operational: At least four methods purport to quantify "dynamic stability" in human walking. The first, and most commonly reported, method quantifies variability (standard deviations or coefficients of variation) of step or stride data such as step length, stride width, and step time. Advocates of this approach contend that increased variability provides a measure of "instability" when it is significantly different from control data. A second method uses clinical tests or diagnostic functional tests (DFTs) to predict fall risk through correlations to prospective results. Depending on the DFT a cut-off score is used to indicate the level of fall risk. A third method follows a dynamical systems approach (DSA) borrowed from engineering and physics to quantify multi-dimensional, state-space variable consistency, based on an observed limit-cycle, and response to perturbations. The fourth method, recently introduce by Hof (2005), uses an inverted pendulum model (Donelan, Shipman et al.) to quantify dynamic stability margins (DSM). The result of the IPM approach is a measure of COM control that is related to step placement during walking. This is generally reported in centimeters and includes the velocity of the COM toward the margins of the BOS in the calculation (equation 1-1).

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Vita

Shawn James Scott was born in Seattle, Washington. After graduating from Meridian High School, Laurel, Washington, he entered Western Washington University in Bellingham, Washington and received a Bachelor of Art degree in June 1990. In November of 1990 he married Laura K. Lindsay. They have three sons, a Godson, and a Labrador retriever. In January 1991 his Army Reserve unit deployed to Saudi Arabia as part of Operation Desert Shield/Storm. He completed a Master's Degree in Physical Therapy in June 1993 and entered into a career as an Army Medical Specialty Corps Officer. During the next 12 years, he and his family were stationed in Washington State, Texas, Germany, and Georgia. He deployed to Kosovo for six months in 1999 as part of a peacekeeping mission. During his time at Ft. Benning, Geogia, Shawn participated in research projects for the Army Physical Fitness School. He co-authored a chapter on developing physical fitness programs for a Recruit Medicine textbook and also co-authored three journal articles and two technical reports. In August 2005 he entered Graduate School at the University of Texas at Austin. Shawn is currently a Lieutenant Colonel in the Army and the Chief of Physical Therapy at Ft. Jackson, South Carolina.

Permanent address: 3404 Ashmere Cove, Round Rock, TX 78681

Current mailing address: 16 Paddock Chase, Irmo, SC 29063

This thesis was typed by: Shawn J. Scott